

Medicare Managed Care Manual

Chapter 3 – Marketing---**DRAFT** (5/12/05)

(Rev. 60, 08-20-04)

Table of Contents

10 - Introduction

10.1 - HIPAA Considerations

20 - Marketing Review Process

20.1 - Marketing Review Process for Multi-Region Organizations

20.2 - Employer Group Marketing Review Process

20.3 – Streamlined Marketing Review Process

20.4 – Time Frames for Marketing Review

20.5 – File & Use Certification Process

20.5.1 Materials Eligible for File and Use Certification

20.5.2 Materials Not Eligible

20.5.3 Acceptable Materials

20.5.4 File and Use Certification Process

20.5.5 Retrospective Reviews

20.5.6 Loss of File and Use Certification Privileges

20.5.7 Use of the Health Plan Management System (HPMS) Marketing module

20.5.8 List of File and Use Eligible Materials

20.5.9 Model of File & Use Certification

20.6 File & Use Eligibility

30 – Guidelines for Advertising and Pre-Enrollment Materials

30.1 - Guidelines for Advertising Materials

30.2 - Guidelines for Pre-Enrollment Materials

30.3 - *“Must Use/Can’t Use/Can Use” Chart*

40 - Guidelines for Post-Enrollment Materials

40.1 - General Guidance for Post-Enrollment Materials

40.1.1 - Use of Model Post-Enrollment Materials

40.1.2 - Use of Standardized Post-Enrollment Materials

40.1.3 - Model Annual Notice of Change (MA, MA-PD,)

40.2 - Specific Guidance About Provider Directories

40.3 - Specific Guidance About Drug Formularies

40.4 - Conducting Outreach to Dual Eligible Membership

- 40.4.1 - General Guidance on Dual Eligibility
- 40.4.2 - Guidelines for Outreach Program
- 40.4.3 - Submission Requirements
- 40.4.4 - CMS Review/Approval Process
- 40.4.5 - Model Direct Mail Letter
- 40.5 - Specific Guidance for the Standardized Summary of Benefits (SB)
 - 40.5.1 – Summary of Benefits for Medicare Advantage Organizations*
 - 40.5.2 - Summary of Benefits for Cost Plans
 - 40.5.3 - Requests to Change Hard Copy Summary of Benefits
- 40.6 – Specific Guidance on the Evidence of Coverage*
- 50 - Guidelines for Promotional Activities
 - 50.1 - General Guidance About Promotional Activities
 - 50.1.1 - Nominal Gifts
 - 50.1.2 - Referral Programs
 - 50.1.3 - Health Fairs and Health Promotional Events
 - 50.1.3.1 - Employer Group Health Fairs
 - 50.1.3.2 - CMS-Sponsored Health Information Fairs
 - 50.1.3.3 - Allowable Actions for Medicare Advantage Organizations
 - 50.2 - Specific Guidance About Provider Promotional Activities
 - 50.3 - Specific Guidance About the Use of Independent Insurance Agents*
 - 50.3.1 - Guidance on state licensure of MA marketing representatives*
 - 50.4 - Answers to Frequently Asked Questions About Promotional Activities
- 60 - Other Marketing Activities
 - 60.1 - Specific Guidance on marketing Activity for Special Needs Plan (SNP)*
 - 60.2 - Specific Guidance About Value-Added Items and Services*
 - 60.2.1 - Restrictions on Value-Added Items and Services
 - 60.2.2 - Relationship of Value-Added Items and Services (VAIS) to Benefits and Other Operational Considerations
 - 60.2.3 - Value Added Items and Services Provided to Employer Groups
 - 60.2.4 - Application to §1876 of the Social Security Act (the Act) Cost Plans
 - 60.2 - Marketing of Multiple Lines of Business
 - 60.2.1 - HIPAA and the Marketing of Multiple Lines of Business
 - 60.3 - Third Party Marketing Materials
 - 60.3.1 - Benefit Providing Third Party Marketing Materials
 - 60.3.2 - Non-Benefit/Service Providing Third Party Marketing Materials
 - 60.4 - Marketing Material Requirements for Non-English Speaking Populations (QISM Standard 2.3.3.2)

60.5.1 - Review of Marketing Materials in Non-English Language or Braille

60.5.2 Model Attestation

Endnotes

10 - Introduction

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This chapter explains requirements for marketing.¹ The intent of this chapter is to:

- Expedite the process for CMS' review of marketing materials;
- Conserve resources by avoiding multiple submissions/reviews of a document prior to final approval;
- Ensure consistent marketing review Bids across the nation; and
- Enable Medicare health plans to develop accurate, consumer friendly marketing information that will assist beneficiaries in making informed health care choices.

This chapter is organized as follows:

Section 20 -- Guidance on the marketing review process

Section 30 -- Guidelines for advertising and other pre-enrollment materials

Section 40 -- Guidelines for post-enrollment (beneficiary notification) materials

Section 50 -- Guidelines on promotional activities, including health fairs and sales presentations

Section 60 -- Guidelines for other marketing activities, such as marketing value added items and services and multiple lines of business

Marketing materials, in general, are informational materials targeted to Medicare beneficiaries that promote the Medicare health plan or any plan offered by the Medicare health plan, or communicate or explain a Medicare health plan.² (See 42 CFR 422.80(b).) The definition of marketing materials extends beyond the public's general concept of advertising materials to include notification forms and letters used to enroll, disenroll, and communicate with the member on many different membership scenarios. Press releases are not considered to be marketing material; however, the CMS does require that one disclaimer be used on press releases during certain times of the year. This requirement is discussed in §30.1.A, Item # 7.

Health education materials are generally not under the purview of CMS marketing review. However, if such materials are used in any way to promote the organization or explain benefits, then they are considered marketing materials and must be approved before use. If there is any commercial message or beneficiary notification information in a health education piece, it must be reviewed by CMS.

NOTE: The CMS considers the Internet as simply another vehicle for the distribution of marketing information. Therefore, all regulatory rules and requirements associated with all other marketing conveyances (e.g., newspaper, radio, TV, brochures, etc.) are applicable to Medicare health plan marketing activity on the Internet. The CMS marketing review authority extends to all marketing activity (both advertising, pre-enrollment, and post-enrollment activity) the Medicare health plan pursues via the Internet. The specific requirements that apply depend on the type of material. For example, the advertising guidelines in §30.1 would apply to postings on the Internet that fall within the definition of advertising, *please see each specific section*.

According to 42 CFR 422.111(f) (12) to the extent that a MA organization has a web site, web page, or provides MA plan information through the Internet, then it must also post copies of its Evidence of Coverage, Summary of Benefits and information on the contracted providers network, i.e., (names, addresses, phone numbers, specialty) on an Internet web site. Such posting does not relieve the MA organization of its responsibility under Section 422.111(a) to continue to provide hard copies to enrollees as detailed in §40.2, 40.5 and 40.6.

The following are requirements regarding the establishment of a name for a MA plan:

1. Beneficiaries with disabilities must be considered part of the audience that any marketing strategy is intended to reach. Specifically, and in light of the publication of the final MA regulation, MA organizations may not use plan names that suggest that a plan is available only to Medicare beneficiaries age 65 or over, rather than to all beneficiaries. This prohibition generally bars plan names involving terms such as “seniors,” “65+,” etc. In fairness to MA organizations with an existing investment in a plan name, the CMS will allow the “grandfathering” of MA plan names established before the final rule took effect (i.e., before June 29, 2000).
2. MA organizations are permitted to use ethnic and religious affiliation in their plan names, as long as the legal entity offering the plan has a similar proper name/affiliation. For instance, if a plan were affiliated with the Swedish Hospital of Minnesota, it would be permissible for the plan to use the tag line, “Swedish Plan, offered by Swedish Hospital System of Minnesota.”
3. *MA organization* can use the term “Medicare” **or** the term “Advantage” in their plan names. Furthermore, all plans in existence as of January 1, 2004, who had the name “*MA organization*” may continue to use that name indefinitely. However, new plans are not allowed to do business under the name “Medicare Advantage.”

If an organization chooses to retain the Medicare Advantage plan name it must insert the company name before “Medicare Advantage” (i.e., Acme Medicare Advantage plan) beginning with all 2005 plan year materials. This will help prevent any confusion with the national Medicare Advantage program.

10.1 - HIPAA Considerations

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On April 14, 2003, new Federal rules governing the privacy of health data *became* enforceable. The rule “Standards for Privacy of Individually Identifiable Health Information” is found at 45 CFR Part 164. Health plans/MA organizations may use or disclose their members’ protected health information as permitted by that rule. Specifically, they may use or disclose this information without beneficiary authorization for treatment, payment or health operations (as those terms are defined by the rule) and for a number of public policy purposes, such as public health and research, recognized in the rule. Health plans/MA organizations are not required to obtain authorization from beneficiaries prior to marketing their plan benefit packages. For additional information regarding HIPAA, go to <http://www.hhs.gov/ocr/hipaa/>.

20 - Marketing Review Process

(Rev. 42, 01-09-04)

Marketing review consists of:

- Pre-approval of marketing materials before they are used by the health plan/MA organization;
- Review of on-site marketing facilities, products, and activities during regularly scheduled contract compliance monitoring visits;
- Random review of actual marketing pieces as they are used in/by the media;
- Retrospective review of marketing materials approved under the streamlined marketing review process; and
- “For-cause” review of materials and activities when complaints are made by any source.

Marketing materials, once approved, remain approved until either the material is altered by the organization or conditions change such that the material is no longer accurate. The CMS may, at any time, require an organization to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time.

The CMS reviews marketing materials according to 42 CFR 422.80(c)(4), to ensure that the marketing materials “are not materially inaccurate or misleading or otherwise make material misrepresentations.” This means that CMS does not disapprove marketing materials based on typographical or grammatical errors. It is the organization’s decision to maintain professional excellence by producing marketing materials that do not contain typographical or grammatical errors.

Submission of Marketing Materials to Regional Offices

All CMS Regional Offices accept marketing material submissions by mail, fax, and e-mail.

When sending materials by e-mail, if the material is over 5 pages long you must also mail the material to the Regional Office. The 5-page requirement refers to the length of the marketing material and does not include the Marketing Material Transmittal Sheet that you may be submitting with the marketing material. The mailing requirement also applies to materials that are of large size, such as draft posters or full-page ads. These materials should be sent by overnight or priority mail. **NOTE:** Some Regional Offices may be equipped to accept e-mail submissions of greater than 5-pages in length without requiring

that a hardcopy submission also be mailed. Your Regional Office will notify you if this is the case.

All Regions will accept e-mail submissions in Microsoft® Word or portable document format (pdf) format. If you have a document in a different format, you should contact the Region to determine whether it can accept that format by e-mail.

When faxing materials to the Regional Office, please call your Regional Office Managed Care Specialist/Plan Manager prior to sending the fax. Under normal circumstances a submission of over 5 pages long should not be faxed to the Regional Office. However, if you need to fax a long piece of marketing material to the Region, you should notify the Regional Office Managed Care Specialist/Plan Manager to let them know that the material is over 5 pages long, prior to sending the fax.

If you send in marketing material in multiple formats (e.g., mail and e-mail), you should indicate on the marketing material that it is being submitted in multiple formats.

Marketing Material Identification Systems

The following requirement applies to all marketing pieces **except** television and radio ads, outdoor advertisements, and banner/banner-like ads.

Health plans/MA organizations must use the system mandated by the reviewing RO for identifying marketing materials submitted to CMS. If the reviewing RO does not have a system, health plans/MA organizations may use their own system for identifying marketing materials. The health plan identifier should appear on the lower left or right side of the marketing piece. After the RO approves the marketing piece, the approval date (month/year) should always be posted to the marketing piece. The approval date is the date on the CMS approval notice.

20.1 - Marketing Review Process for Multi-Region Organizations

If you are an organization that operates in more than one of CMS' Regional Offices, your marketing review approach (i.e., lead region, local regions, etc) is determined by the agreement your organization makes with CMS Multi-Region Team management.

The Multi-Region MA organization must ensure that materials submitted are consistent with the requirements in this chapter.

In addition, the Multi-Region MA organization must distribute final copies of its national marketing materials, within a time frame to be determined by its CMS Multi-Region team, to the lead and local ROs with a dated cover letter, which identifies the recipients.

NOTE: Although the local ROs may no longer play a part in approval of the national marketing piece, the health plan/MA organization must send a final copy of the approved material to the local ROs for their records.

20.2 - Employer Group Marketing Review Process

(Rev. 42, 01-09-04)

Under the authority granted in §617 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, CMS has waived all MA organizations from having to follow the requirements under 42 CFR 422.80(a) for employer group members. This waiver applies to members of employer-group only plans and to members of individual plans who have joined the individual plan through their employer (i.e., the employer has contracted with the MA organization for its employees/retirees to join the individual plan). This means that MA organizations need not have CMS pre-approve marketing materials prepared by MA organizations designed for members of employer groups. The waiver does not include waiving the disclosure requirements at 42 CFR 422.111, which outline what information must be provided to members annually and at the time of enrollment. While MA organizations do not need to have employer group materials pre-approved under this waiver, they still must disclose the information at 42 CFR 422.111(b) to all members (e.g., plan benefits, prior authorization rules, grievance and appeals procedures, etc.).

The CMS will assume that MA organizations have chosen to use this waiver unless we hear otherwise from the MA organization. All MA organizations will be required to send informational copies of employer group-specific marketing materials to the Regional Office/lead region within 14 days of their release/use. (Regional Offices will not be reviewing these materials; instead, they will keep them on file in the event any inquiries are received about them.)

The MA organization assumes responsibility for the accuracy of the employer group marketing materials, including making any corrections to those materials when necessary. The MA organization is expected to continue to follow the guidelines within this chapter when preparing its marketing materials. In the unusual circumstance of an organization knowingly releasing/distributing incorrect or false marketing materials, sanctions, and or/fines may be imposed on that organization.

20.3 – Streamlined Marketing Review Process

***IMPORTANT NOTE:** Organizations must not use this streamlined review process until further notice.

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The CMS offers a streamlined marketing review process to MA organizations and demonstrations for certain marketing materials in order to ensure that the materials can be

available to Medicare beneficiaries in time to make decisions about their health insurance coverage. In particular, the streamlined marketing review process only applies to marketing materials developed for the Fall campaign (i.e., the Annual Notice of Change (ANOC), the Summary of Benefits (SB), and materials necessary to develop an annual enrollment period marketing package in the Fall to encourage members to join the plan) and marketing materials developed to notify members of any mid-year benefit enhancements.

An organization may choose one of two ways to have materials reviewed and approved under the streamlined process.

Option 1: MA organizations can obtain approval of their plan marketing materials based on submitted Bids.

Under this option the CMS RO will review the materials based on the submitted (i.e., not yet approved) BIDSP information. The organization must submit all sections of the SB for review.

Under this option, if the organization resubmits an BIDSP that includes changes/corrections that affect marketing materials that are still under review by CMS, the organization must re-submit the material to CMS containing the changes/corrections.

Option 2: An MA organization can submit materials without cost sharing/benefit information contained in the “template” material.

Under this option the RO will review the template and the organization will be responsible for inserting the accurate cost sharing/benefit information after approval is received. Under this option, the organization need only submit section 3 of the SB for review and approval.

If the template the organization sends to the RO will vary in any way, it must describe those variations to the RO when submitting it for review (for example, if the provider directory template will be broken down into sub-versions for larger counties or will differ for plans with hospital tiering, the organization must alert the RO to this fact).

Organizations can submit the template marketing materials for review before the date that MA organizations may submit Bids to CMS, since these materials would not contain the BIDSP information.

Regardless of which option is chosen, keep in mind the following:

- The organization must use the “pending Federal approval” disclaimer on the materials until the BIDS is approved by CMS. Once the BIDS is approved, the MA organization must remove the disclaimer.

- If the organization resubmits an BIDSP that includes changes/corrections that affect marketing materials already approved (or under review, for organizations following option #2), the organization is responsible for correcting all marketing materials to reflect these BIDSP changes. The material does not need another approval by CMS.
- Any organization that uses marketing materials containing errors (e.g., the benefit or cost sharing information differs from that in the approved BIDSP) will be required to correct those materials for prospective members and send errata sheets/addenda to current members before January 1. The CMS will conduct a retrospective review of a sample of MA plan materials and will notify the organization if corrections are necessary. The MA organization will be expected to conduct a self review of all other marketing materials for plans not included in the sample and to issue CMS-approved correction notices as necessary.

20.4 – Time Frames for Marketing Review

(Rev. 35, 10-31-03)

This chapter deals primarily with the pre-approval of marketing materials. As outlined in regulations at 42 CFR 422.80(a) and 417.428(a)(3), health plans/MA organizations may not distribute any marketing materials or election forms or make them available to individuals eligible to elect a plan offered by a health plan/MA organization unless such materials have been submitted to the CMS at least 45 days prior to distribution and the CMS has not disapproved the materials. A health plan/MA organization may also distribute materials before 45 days have elapsed if prior approval has been granted by the CMS. Guidelines for CMS review are further described at 42 CFR 422.80(c) for MA organizations and 417.428(a) for cost plans.

While not required to do so by law, the CMS will make every effort to review materials prepared by cost plans within 10 days if they have followed CMS' cost plan model language without modification. However, while the CMS will try to review the cost plan marketing materials within 10 days, the cost plan must not consider the material deemed approved if 10 days pass and it has not received approval or disapproval from the CMS since, by law, 45 days must pass before the material may be deemed approved.

Exception to the 45-day marketing review rule:

- **MA Organization Exception:** When an MA organization follows CMS model language without modification, the CMS must review the material within 10 days (as opposed to the usual 45 days). The CMS must make a determination on the material within 10 days or else the marketing material is deemed approved.

To alert the CMS reviewer to the need for a 10-day review, the health plan/MA organization must indicate on the submission that it has followed the CMS model without modification and is requesting a 10-day review.

The 10-day review period only applies when the health plan/MA organization has followed the CMS model without modification. “Without modification” means the health plan/MA organization used CMS model language verbatim and only used its own language in areas where we have given them license to include their own information (such as where they are asked to include their plan-specific benefits). It also means that the health plan/MA organization has followed the sequence of information provided in the model in its own marketing material. In these cases, the regional office may only need to review the health plan’s/MA organization’s language in order to make a determination on the marketing material within the 10-day time frame.

NOTE: An MA organization’s Evidence of Coverage (EOC) cannot be approved until the organization’s BID (BIDS) is approved. If an MA organization submits an EOC that follows the CMS model without modification for review early in the year (prior to BIDS approval), the Regional Office will review and approve all non-BIDS-related information within the 10-day review period, and will conduct a cursory review of all BIDS-related information based on the MA organization’s BIDS submission. However, the Regional Office will need to disapprove the release of BIDS-related marketing material within the 10-day window, since there is no basis for approving it, and indicate that the material will be approved upon approval of the BIDS. The Regional Office will need to promptly review and approve these marketing materials upon approval of the BIDS.

20.5 – File & Use Certification

CMS has streamlined the marketing review process for both MA and Part D (See Part D guidance) marketing materials. However, the marketing materials that have the highest impact on Medicare beneficiaries will remain under the 45 day (10 days if model language is used without modification) review process. Regulations at – 42 (C.F.R.), section. 422.80 (a) (2) (ii) - implementing the Medicare Modernization Act of 2003 (MMA) add a certification category for the review of marketing materials. The guidelines in this section provide that beginning June 7, 2005, all organizations must certify that they followed all applicable marketing guidelines or used model language for marketing materials as specified by CMS unless the organization requests a waiver. Eligibility status for certain marketing materials will still be available for plans that can demonstrate to CMS that they continually meet a particular standard of performance (Section 20.6).

20.5.1 - Materials Eligible

The materials that are eligible for the File and Use Certification process consist of: (1) all advertisement materials (2) provider/pharmacy directories and (3) certain CMS model letters without modifications (i.e., enrollment/disenrollment, claims, organization determinations, appeals, grievances model letters). See Section 20.5.3 for a detailed list of marketing materials that are eligible for the File and Use Certification process. The materials that qualify under the File and Use Certification can be distributed 5 calendar days after the day of submission to CMS, but no earlier than any date CMS may establish

for use of any particular material. The organizations that do not have File and Use Eligibility status must use the File and Use Certification process for all marketing materials in the File and Use category unless the organization requests a waiver.

20.5.2 - Materials Not Eligible for File and Use Certification Process

*Materials that **are not eligible** for file and use certification are materials that CMS determines pose a significant risk to a Medicare beneficiary if they are inaccurate in any way. These documents are the Summary of Benefits (Section 3), Evidence of Coverage, Member Handbooks, Annual Notice of Change (ANOC) and Modified ANOC, Mid- year Benefit Enhancement Notices, the Individual Enrollment Form and the Abbreviated Enrollment Form and the Disenrollment Form and any other documents defined by CMS in Section 20.5.3. The materials that are not eligible for the file and use certification process will remain under either the 45/10 review process or the file and use eligible process outlined in Section 20.6.*

20.5.3 – Acceptable Material

All material that is not materially inaccurate or misleading or otherwise makes a material misrepresentation, which means that the material follows the guidelines delineated in this Chapter. It also means that, as submitted, the materials do not need to be changed to avoid adverse impact on a beneficiary's decision to elect the plan or to disenroll and/or to avoid leading a member to believe that he/she could not get coverage for a covered service.

Examples of changes that would result in a material being unacceptable include failing to include a disclaimer that a particular benefit is not available to everyone or providing inaccurate premium or benefit information.

Example of changes that would not cause a material to be unacceptable (i.e., it would still be “acceptable”) might be to not adhere to font-size requirements for an ad or to provide incorrect dates or times for a sales presentation. Keep in mind that persistent errors in sales presentation dates or persistent failure to adhere to font size requirements could cause CMS to begin considering an organization's materials to be unacceptable.

20.5.4 - Certification Process

Each organization must submit the File and Use Certification marketing materials to CMS at least 5 calendar days prior to distribution and certify that the materials have complied with the marketing guidelines. As required, each organization is responsible for ensuring the accuracy of its marketing materials, and adherence to CMS marketing guidelines. The Certification form must be submitted to CMS RO via HPMS prior to submitting materials under the File and Use Certification process. Certification forms or reason(s) to requests a Certification waiver should be received by July 1, for every calendar year.

CMS will only verify that the marketing materials submitted under the File & Use Certification follows the following administrative requirements: 1) CMS has received a signed Certification form from the Organization's CEO/CFO (described below); 2) materials submitted qualify for the File and Use Certification process; 3) a completed transmittal form is attached to the materials (unless it is electronically submitted through HPMS); and 4) all materials include the plan contract # [i.e. H#XXXX, D# XXXX] as a prefix to the marketing materials identification number.

Organizations are contractually responsible for being in compliance with the marketing requirements per 42 C.F.R. 422.80 and 422.111. This requirement has not changed the responsibilities of the organizations. The Organization Advertising Materials/Model Documents File and Use Certification form (See section 20.5.9 for CMS model) states that the Organization agrees that all advertising materials and model documents that are used are accurate, truthful and not misleading. As required, each organization is responsible for ensuring the accuracy of its marketing materials, and adherence to CMS standard marketing guidelines. The certification form must be signed by the Organization CEO/CFO and the certification is effective until further notice from CMS.

20.5.5 – Retrospective Reviews

The retrospective review process will be consistent with the review process that CMS conducts on File and Use Eligibility.

All materials submitted through the File and Use Certification process will be subject to a retrospective review process. On an ongoing basis the CMS RO will select a random sample of eligible materials that an organization submitted to the RO over the prior 6 months under the File and Use Certification process. In addition, CMS will investigate any marketing complaints that are received to verify if they are valid or invalid marketing violations. CMS may require that the organization prepare an addendum or reissue File and Use marketing materials at no expense to the Government, if it is found to not conform to the marketing requirements in the organization's contract.

Plans will be held accountable for reimbursement of a Medicare beneficiary's liability if the beneficiary was affected based on incorrect marketing materials. Criteria for compliance is available in the Medicare Managed Care Manual Chapter 3 which is developed by CMS and should be used, along with the statutory requirement outlined in Section 1851(h) of the Social Security Act and further guidance provided in the 42 C.F.R. sections 422.80 and 422.111 for Medicare Advantage organizations. The marketing guidelines mentioned in this document are periodically updated and provided to the organization by CMS. Failure to conform to the marketing guidelines may result in a corrective action to protect the interest of the Medicare enrollees. The corrective action will be appropriate to the circumstances as outlined in the marketing section of the organization contract with CMS.

20.5.6 – Loss of File and Use Certification Privileges

An organization may lose File & Use Certification status if it uses materials that do not meet the requirements of the Chapter 3, Marketing Guidelines of the Medicare Managed Care Manual. The Regional Office will notify the organization in writing if File and Use Certification privilege is being revoked. The loss of File and Use Certification privilege does not mean that an organization may never again take an advantage of File and Use Certification. If CMS revokes an organization's File and Use Certification privilege, the organization may get back on File and Use Certification once at least two calendar quarters have passed since its privilege was taken a way. If an organization loses File and Use Certification privilege twice, it may not get back on File and Use Certification for at least one year from the privilege was taken a way the second time.

20.5.7 - Use of the Health Plan Management System (HPMS) Marketing Module

CMS recommends that all organizations submit marketing materials to the Regional Office/Part D Contractor through the Health Plan Management System (HPMS). The HPMS Marketing Module is an automated tool that an organization uses to enter, track, and maintain marketing materials submitted to CMS for review. HPMS has the capability to accept electronic files of the actual marketing materials. The marketing review timeline starts once the marketing materials are submitted into HPMS. The Marketing Module User's Guide provides extensive information on HPMS and is located at <http://gateway.cms.hhs.gov>.

20.5.8 – List of File and Use Eligible Materials

Non-Model:

- *All Advertising Materials*
- *Provider Directory*
- *Plan generated Surveys/Assessments*
- *Other Member Materials*

Model:

- *Acknowledgement of Receipt of Completed Enrollment Form*
- *Request for Information for Enrollment*
- *Confirmation of Enrollment*
- *MCO Denial of Enrollment*
- *CMS Rejection of Enrollment*
- *Notice to Sending out Disenrollment Form*
- *Acknowledgment of Receipt of Voluntary Disenrollment Request from Member*
- *Confirmation of Voluntary Disenrollment Identified Through Reply Listing*
- *Verification of Change in Address*
- *Disenrollment due to permanent Move*
- *Notice of Upcoming Disenrollment Due to Out of area*

- *Final confirmation of Disenrollment due to Out of area*
- *Disenrollment Due to loss of Part A and/or Part B Coverage*
- *Disenrollment Due to Death*
- *Offering Beneficiary Services, Pending Correction of Erroneous Death Status*
- *Offering Beneficiary Services, Pending Correction of Erroneous Part A/B Termination*
- *Closing Out Request for Reinstatement*
- *Failure to Pay Plan Premiums – Advanced notification of Disenrollment or Reduction in Coverage*
- *Failure to Pay Plan Premiums – Notification of Involuntary Disenrollment*
- *Failure to Pay Plan Premiums – Confirmation of Involuntary Disenrollment*
- *Failure to Pay Plan Premiums – Notice of Reduction in Coverage*
- *Appeals & Grievance Forms and Letters*

20.5.9 Model of File & Use Certification

FILE AND USE CERTIFICATION FORM –

MODEL DOCUMENTS FOR MEDICARE HEALTH PLANS

Pursuant to the contracts(s) between the Centers for Medicare & Medicaid Services (CMS) and (insert organization name), hereafter referred to as the Medicare Health Plan governing the operations of the following health plan: (insert plan and Contract number), the Medicare health plans hereby certify that all eligible materials are accurate, truthful and not misleading. Organizations must use the File and Use Certification and agrees to retract and revise any materials (without cost to the government) that are determined by CMS to be misleading or inaccurate or do not follow established marketing guidelines. In addition, organizations may be held accountable for any beneficiary financial loss as a result of mistakes in marketing materials with a negative beneficiary impact. Compliance criteria are set forth in CFR 422.80, 422.111 for MA plans and should be used with the Medicare Managed Care Manual, Chapter 3.

I agree that CMS may inspect any and all information including those held at the premises of the Medicare Health Plan to ensure compliance with these requirements.

I further agree to immediately notify CMS if I become aware of circumstances which indicate noncompliance with the requirements indicated above.

SIGNATURE

NAME & TITLE [CEO, CFO, or delegated])

On behalf of

Name of Medicare Health Plan

Date

This certification form must be signed and received by the Regional Office Plan Managers prior to submitting materials under the File and Use Certification Process. Once the File and Use Certification form is received, it is effective until further notice from CMS.

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20.6 – File & Use Eligibility

The File & Use Eligibility program is designed to streamline the marketing review process. Under this process, Medicare Advantage organizations, demonstrations, and Medicare Cost plans that can demonstrate to CMS that they can continually meet a particular standard of performance will be able to publish and distribute certain marketing materials without prior CMS approval.

File & Use Policies and Procedures

Either the parent company (which could be a multi-site organization but is not always a multi-site organization) or the contracting entity can request that the Regional Office grant File & Use Eligibility status to the contracting entity. File & Use Eligibility status is given to and maintained by a contracting entity (i.e., also known as the “organization,” this is the entity that is granted a single H #). All plans (PBPs) within a single H # will be a part of the File & Use Eligibility program once the single H # is on File & Use Eligibility status. Individual contracting entities can maintain this status even if other entities in the parent company do not. For example, if a parent company operates in a number of different States (i.e., has several different H #s), and File & Use Eligibility status is given to only a subsidiary operating in one State, that subsidiary organization may maintain its File & Use Eligibility status, even if the subsidiaries in other States do not.

The CMS Regional Office that is the lead for that multi-region company maintains File & Use Eligibility status for multi-region company. If File & Use Eligibility status is granted to a multi-region company, it means that the lead Regional Office (i.e., the “multi-region team lead”) has granted File & Use Eligibility privileges to all national materials developed by the multi-region company. The local Regional Office must still review local materials, unless the local contracting entity has been granted File & Use Eligibility status by the local Regional Office.

Some organizations use many non-English marketing materials. Once a contracting entity is granted File & Use Eligibility status, both the English and the non-English materials are included within the File & Use Eligibility program. See section 60.4.1 for detail in review of marketing materials in non-English or Braille.

Eligible Material: All advertising and pre-enrollment materials used to market the health plan to potential enrollees through a format of general circulation, all enrollment and disenrollment letters, and any post-enrollment materials that do not describe benefits and/or cost sharing and/or plan rules.

Materials that are not eligible for the File & Use Eligibility program are materials that CMS believes pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These are post-enrollment materials (beneficiary notification materials) that describe benefits and/or cost sharing and/or plan rules and enrollment and disenrollment

forms. These include materials such as the Evidence of Coverage, Summary of Benefits, and other member notices (such as the Annual Notice of Change, provider termination notices, claims denial notices, etc.).

Acceptable: All material that is not materially inaccurate or misleading or otherwise makes a material misrepresentation, which means that the material follows the guidelines delineated in Chapter 3 of the Medicare Managed Care Manual. It also means that, as submitted, the materials do not need to be changed to avoid adverse impact on a beneficiary's decision to elect the plan or to disenroll and/or to avoid leading a member to believe that he/she could not get coverage for a covered service.

Examples of changes that would result in a material being unacceptable include failing to include a disclaimer that a particular benefit is not available to everyone or providing inaccurate premium or benefit information.

Example of changes that would not cause a material to be unacceptable (i.e., it would still be "acceptable") might be to not adhere to font-size requirements for an ad or to provide incorrect dates or times for a sales presentation. Keep in mind that persistent errors in sales presentation dates or persistent failure to adhere to font size requirements could cause CMS to begin considering an organization's materials to be unacceptable.

Eligibility for the File & Use Eligibility Program

The File & Use Eligibility status is only granted on a calendar quarter basis (i.e., January 1, April 1, July 1, or October 1).

Organizations that use the File & Use Eligibility program are agreeing to retract and revise any materials that are later determined by CMS to be misleading or inaccurate, or do not follow the guidelines outlined in Chapter 3 of the Medicare Managed Care Manual.

To become eligible for or to stay on the File & Use Eligibility program, an organization must meet the following criteria.

How to Attain File & Use Eligibility Status

The organization must request in writing to the Regional Office to be on File & Use Eligibility no later than 30 days prior to each calendar quarter.

The CMS Regional Office will select a random sample of eligible materials that the organization submitted to the Regional Office for review over the prior 6 months. In case where zero material is found during prior 6 months, the CMS Regional Office will go back further additional 3 months to review the materials.

The Ninety (90) percent of these materials must be "acceptable," according to File & Use Eligibility criteria. This means that while the materials were pre-approved by the

Regional Office, they would have met the definition of “acceptable” even if the Regional Office had not reviewed them.

The contracting entity (i.e., the H#) must have been in the Medicare program for at least the last 18 months. One exception to this 18-month rule is if the parent company has been in the program for over 18 months and the parent company requests that the contracting entity be given File & Use Eligibility status even though the H# has not been in the Medicare program for 18 months.

The CMS Regional Office Branch Chief will notify the organization of the Region’s decision in writing 7 days prior to next calendar quarter.

If the organization disagrees with the Regional Office’s decision, it can notify the National File & Use Eligibility Coordinator of its disagreement. The National File & Use Coordinator and the Marketing Product Consistency Team (PCT) will review the decision made by the Regional Office and notify the organization in writing if the decision is upheld or overturned.

How to Maintain File & Use Eligibility Status

Once an organization is on the File & Use Eligibility program, it must do the following to maintain that status:

The ninety (90) percent of eligible materials used under the File & Use Eligibility program during the prior 6 months must be “Acceptable” per File & Use Eligibility criteria (as determined by the Regional Office). The Regional Office will conduct semi-annual reviews of random sample of materials filed under the File & Use Eligibility program to determine whether the materials meet this performance standard. In markets where foreign language marketing materials are used, the CMS Regional Office may select such pieces in the sample that will be reviewed.

The organization must follow the procedures outlined in the section below entitled “Procedures to Follow When using File & Use Eligibility.”

The organization must continue to submit to CMS materials that are not eligible for the File & Use Eligibility program in accordance with the requirements outlined in Chapter 3 of the Medicare Managed Care Manual. (For clarification, see the definition of “Eligible Material” above.)

Procedures to Follow When using File & Use Eligibility

The organization must provide CMS with copies of all final materials within 5 calendar days prior to their distribution. The “final” materials are the copies that will be sent to the printer, or the comparable copies that are provided for reproduction.

All organizations must specify the expected date of initial distribution or publication when filing materials with CMS.

All organizations must clearly indicate on the front cover of the Marketing Material Transmittal sheet that the material is being filed as a “File & Use Eligibility” material.

Upon receipt of the materials, CMS will log them into the Marketing Module of the Health Plan Management System.

Organizations that have File & Use Eligibility privileges may still submit using the standard procedure for prior approval any eligible materials with respect to which they would like guidance from CMS. This may prevent an organization from losing File & Use Eligibility privileges.

If the organization submits materials under the File & Use Eligibility program but later decides it does not want to use the materials, it must notify the Regional Office in writing that it no longer intends to use them. This is to ensure that the Regional Office does not review those materials as part of the random sample reviewed during the quarterly review.

Loss of File & Use Eligibility Status

An organization may lose File & Use Eligibility status if it uses materials that do not meet the definition of “Acceptable” and/or, fails to file two or more materials at least 5 calendar days prior to distribution or publication.

The Regional Office will notify the organization in writing if it is in danger of losing File & Use Eligibility status. This notice will indicate that the organization has been placed on a probationary review period and will delineate the length of the probationary period. The length of the probationary period will be determined by the Regional Office on a case-by-case basis, depending on the type and impact of errors identified in marketing materials, but generally will last no less than one month and no more than one calendar quarter in length.

During the probationary period, the organization must send materials to the Regional Office 30 days in advance of their use as opposed to the usual 5 days. The RO will conduct an increased level of spot checks of marketing materials used under the File & Use Eligibility process. In the middle of the probationary period, the Regional Office will provide written notice to the organization indicating whether it has seen improvement during the spot checks of marketing materials, or if the organization is still in danger of losing File & Use Eligibility status. At the end of the probationary period, the Regional Office will notify the organization in writing regarding whether or not the organization may continue with File & Use Eligibility status. If the determination is to terminate File & Use Eligibility status, this notice will provide the organization with 10-day advance notice of the termination.

The termination of File & Use Eligibility status does not mean that an organization may never again obtain File & Use Eligibility status. If CMS terminates an organization's File & Use Eligibility status, the organization may request to get back on File & Use Eligibility once at least two calendar quarters have passed since its status was terminated. If an organization loses File & Use Eligibility status twice, it may not request to get back on File & Use Eligibility status for at least one year after the status was terminated the second time.

30 - Guidelines for Advertising and Pre-Enrollment Materials

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The guidelines in this section apply to all advertising and pre-enrollment materials. The section is divided into three subsections:

30.1 -- provides guidelines on advertising materials

30.2 -- provides guidelines on pre-enrollment materials

30.3 -- provides the "Must Use/Can't Use" chart

Guidelines for post-enrollment materials (beneficiary notification materials -- member handbooks, member letters, etc.) are addressed in §40.1.

Medicare health plans may market plans directly to beneficiaries of former Medicare health plans that have chosen not to renew their contracts as long as the marketing does not begin until after the date the beneficiary has received the plan termination letter. Some disclosures are required on pre-enrollment materials – refer to §30.2.A, Item #8.

No Medicare health plan may compare itself to another Medicare health plan by name in either advertising or post-enrollment materials.

30.1 - Guidelines for Advertising Materials

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

Advertising materials can be defined as materials that are primarily intended to attract or appeal to a potential enrollee. They are intended to be viewed quickly by a potential enrollee and are short in length/duration. Specifically, these advertisements are:

- Television ads;
- Radio ads;
- Banner/banner-like ads;

- Outdoor advertising;
- Direct mail (as long as it does not include the enrollment form);
- Print ads (newspaper, magazine, flyers, etc.); and
- Internet advertising.

This section outlines requirements for these types of advertisements.

The following definitions apply to some of the ads addressed in this section:

- **Outdoor Advertising (ODA):** ODA is marketing material intended to capture the quick attention of a mobile audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles, etc.). ODA is designed to catch the attention of a person and influence them to call for detailed information on the product being advertised.
- **Banner Advertisements:** “Banner” advertisements are typically used in television ads, and flash information quickly across a screen with the sole purpose of enticing a prospective enrollee to call the organization for more information. This type of ad does not contain benefit or cost sharing information.
- **Banner-like Advertisements:** A “banner-like” advertisement can be ODA and is usually in some media other than television, is intended to very brief and to entice someone to call the organization or to alert someone that information is forthcoming and, like a banner ad, does not contain benefit or cost sharing information.

The following guidelines apply to advertisements:

A. Language Requirements

1. Disclaimers/Disclosures:

- a. For banner ads, banner-like ads and ODA, Medicare health plans are not required to include **any** disclaimers or disclosures (e.g., lock-in and premium information) on the ads.
- b. For all other advertising materials not listed in a. above, Medicare health plans must include the statement that the organization contracts with the Federal government. Refer to the “Must Use/Can’t Use/Can Use” chart in §30.3 for statements the organization may use.

***IMPORTANT NOTE:** *The below paragraph must **not** be used until further notice.*

If the material references benefits/cost sharing, and is being used under the streamlined review process addressed in §20.3, then the material must also include the disclaimer that the benefits/cost sharing is “pending Federal approval.” With one exception for certain materials (see c. below), no other disclaimers or disclosures (e.g., lock-in and premium information) are required for these advertising materials.

- c. In addition to the disclaimers required in b. above, flyers and invitations to sales presentations that are used to invite beneficiaries to attend a group session with the intent of enrolling those individuals attending must also include the following two statements:

- “A sales representative will be present with information and applications.”
- “For accommodation of persons with special needs at sales meetings, call [insert phone number].”

2. **Hours of Operation:** Medicare health plans must list the hours of operation for customer services and other health plan services anywhere that these phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the organization lists the 1-800-MEDICARE number (24 hours a day/7 days a week). This requirement does not apply to any numbers included on advertising materials for persons to call for more information.
3. **TTY Numbers:** With the exceptions listed below, TTY numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. Medicare health plans can use either their own or State relay services, as long as the number included is accessible from TTY equipment.

Exceptions:

- TTY numbers need not be included on ODA and banner/banner-like ads or in radio ads that include a telephone number.
 - With respect to television ads, the TTY number need not be the same font size/style as other phone numbers since it may result in confusion and cause some prospective enrollees to call the wrong phone number. Instead, Medicare health plans are allowed to use various techniques to sharpen the differences between TTY and other phone numbers on a television ad (such as using a smaller font size for the TTY number than for the other phone numbers).
4. **Reference to Studies or Statistical Data:** Medicare health plans may refer to results of studies or statistical data in relation to customer satisfaction, quality, cost, etc. as long as specific study details are given. At a minimum, study details

that need to be included are the source and dates. (**NOTE:** When submitting the material to CMS for review, unless the study that is referenced is a CMS study [such as CAHPS], the organization must provide the study sample size and number of plans surveyed for review purposes). Medicare health plans may not use study or statistical data to directly compare their plan to another. If Medicare health plans use study data that includes information on several other Medicare health plans, they will not be required to include data on all of the organizations included in the study. However, study details, such as the number of plans included, must be disclosed. Qualified superlatives (e.g., among the best, one of the highest ranked, etc.) may be used. Superlatives (e.g., ranked number one, etc.) may only be used if they are substantiated with supporting data.

5. Physicians and Other Health Care Providers:

- a. If the number of physicians and other health care providers is used in an ad, the ad must include only those physicians and providers available to Medicare beneficiaries. (Medicare cost plans may annotate in materials that members may obtain services from any Medicare provider).
- b. For print ads and direct mail materials:
 1. If a total number of physicians and providers are used in the ad, it must separately delineate the number of primary care providers and specialists included.
 2. If the Medicare health plan uses the name and/or picture of providers and/or facilities to market itself, the provider information may only be used within the context of informing beneficiaries of providers that are associated with the MA organization's delivery system.

6. Preferred Provider Organizations (including PPO Demonstrations) Only:

The following requirements only apply to Internet ads, brochures, and direct mail pieces. They do not apply to television and radio ads, ODA, and banner/banner-like ads.

- **Mandatory Supplemental Benefits:** If a PPO offers benefits, including mandatory supplemental benefits (such as prescription drugs or dental services) that are limited to in-network providers and facilities, marketing materials that mention these benefits must state that not all benefits are available from non-preferred providers.
- **Cost Savings Described in Marketing Materials:** If a PPO states in marketing materials that prospective enrollees may save money if they join the plan, it must acknowledge the added cost of accessing services

out-of-network and/or that using services in-network can cost less than using services out-of-network.

7. **Press Releases:** As stated in §10, press releases are not marketing material. However, if an organization chooses to address any benefit, cost sharing or service area information in a press release before CMS has approved the benefits, cost sharing or service area, it must include the “pending Federal approval” disclaimer in the press release.

B. Formatting Requirements

1. **Font Size Rule:** With the exception listed below, for all written advertising materials footnotes must be the same size font as the majority of the text of the advertisement. The text size is left to the discretion of the organization and can be smaller than size 12-point font, but the majority of the text of the advertisement and footnotes must be the same size font.

Exception:

- Information contained in brochures and direct mail pieces must be no smaller than Times New Roman 12-point or equivalent font. More detail on this requirement is contained in §30.2.
 - If an organization publishes a notice to close enrollment (as required in Chapter 2) in the Public Notices section of a newspaper, the organization need not use 12-point font and can instead use the font normally used by the newspaper for its Public Notices section.
2. **Font Size Rule for Internet Advertising:** Unless an exception regarding font size is noted in #1 above, any advertising materials that a Medicare health plan places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor the Medicare health plan has any control over the actual screen size shown on individuals’ computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the Medicare health plan codes the font for the Web page, not how it actually looks on the user’s screen.

30.2 - Guidelines for Pre-Enrollment Materials

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

“Pre-enrollment” materials provide more detail on the plan (e.g., plan rules, plan benefits, etc.) than what is provided in an advertisement, and generally are used by prospective enrollees to decide whether or not to enroll in a plan. Pre-enrollment materials include both sales and enrollment materials, including the following types of materials:

- Product descriptions used in the sales/enrollment process -- enrollment booklets, sales kits, etc.
- Sales scripts, sales presentations, etc.
- *Direct mail that includes an enrollment form or other enrollment notification such as, notices for facilitated or passive elections.*

At a minimum, prior to enrollment, prospective enrollees should receive information on lock-in/access requirements and a summary of benefits. However, it is preferable to provide more information to help a prospective enrollee make the choice to enroll in a plan.

NOTE: There are other enrollment-related documents that are usually included in sales packages -- such as enrollment applications and the Statement of Understanding. Requirements and models for these documents are addressed in Chapter 2.

NOTE: While the SB and could be viewed as both a pre- and post-enrollment material, we have placed instructions regarding these documents in the post-enrollment section since, at a minimum, it must be sent to current enrollees. Instructions on the SB can be found at §40.5.

The following guidelines apply to pre-enrollment materials:

A. Language Requirements

1. **Lock-In Statement/Access information:** When appropriate for the plan, the concept of “lock-in” must be clearly explained in all pre-enrollment materials. For marketing pieces that tend to be of short duration we suggest: “You must receive all routine care from plan providers” or “You must use plan providers except in emergent care situations or for out-of-area urgent care/renal dialysis.” However, in all written materials used to make a sale, a more expanded version is suggested: “If you obtain routine care from out-of-plan providers neither Medicare nor [name of MA organization] will be responsible for the costs.”

For PPOs, POS plans and, if appropriate, Visitors Programs for any plan type, explain that use of non-plan or non-preferred providers is allowed, but may cost more to the beneficiary.

For Medicare cost plans, enrollees must be informed that after enrollment is effective, in order for them to receive the full coverage offered, services other than emergency and urgently-needed services must be obtained through the HMO or CMP. In the case of cost enrollees, however, they may receive services that are not provided or arranged by their HMO or CMP, but they would be responsible for payment of all Medicare deductibles and coinsurance as well as any additional

charges as prescribed by the Medicare program. They also would be liable for any charges not covered by the Medicare program.

2. **Networks and Sub-networks:** All pre-enrollment marketing materials must clearly explain the concept of networks and sub-networks and the process for obtaining services, including referral requirements.
3. **Hours of Operation:** Medicare health plans must list the hours of operation for customer services and other health plan services anywhere that these phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the organization lists the 1-800-MEDICARE number (24 hours a day/7 days a week).
4. **Identification of All Plans in Materials:** Where MA organizations may file separate/distinct BID (BIDS) Proposals and the Plan Benefit Package (PBPs) cover the same service area (or portions of the same service area), there is no requirement that all plans be identified in all of the MA organization's marketing materials, although MA organizations may identify or mention more than one plan in a single marketing piece at their discretion.
5. **Contracting Statement:** All pre-enrollment materials (and some other materials, as mentioned in §§30.1 and 40) must include a statement that the health plan/MA organization contracts with the Federal government. Refer to the Must Use/Can't Use/Can Use chart in §30.3 for statements the organization may use.
6. **TTY Numbers:** TTY numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. The TTY number must also include the hours of operation, if they are for customer or health plan services. Medicare health plans can use either their own or State relay services, as long as the number is accessible from TTY equipment.
7. **Availability of Alternative Formats:** To ensure that beneficiaries have access to beneficiary education materials in alternative formats (e.g. Braille, foreign languages, audio tapes, large print), *MA organizations* must provide a disclosure on pre-enrollment materials indicating the document is available in alternative formats.
8. **Marketing plans to beneficiaries of non-renewing Medicare plans:** As stated in §30, *MA organizations* may market plans directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the marketing does not begin until after the date the beneficiary has received the plan termination letter. In addition to the targeted message, any pre-enrollment marketing pieces must contain a statement indicating that the Medicare health plan is open to all Medicare beneficiaries eligible by age or disability in the plan's service area.

9. Preferred Provider Organizations (including PPO Demonstrations) Only:

- **Cost Savings Described in Marketing Materials:** If a PPO states in marketing materials that prospective enrollees may save money if they join the plan, it must also acknowledge the added cost of accessing services out-of-network and/or that using services in-network can cost less than using services out-of-network.
- **Preferred and Non-Preferred Benefits:** If a PPO offers benefits for which the coinsurance is the same percentage both in and out of network, the PPO must make it clear in all pre-enrollment material that member responsibility may be greater out of network since the coinsurance is based on the Medicare allowed amount and not on the potentially lower contracted amount.

Also, explain in pre-enrollment materials that with the exception of emergency or urgent care, it may cost more to get care from non-plan or non-preferred providers.

- **Mandatory Supplemental Benefits:** If a PPO offers benefits, including mandatory supplemental benefits (such as prescription drugs or dental services) that are limited to in-network providers and facilities, marketing materials that mention these benefits must state that not all benefits are available from non-preferred providers.

10. **Reference to Studies or Statistical Data:** Reference to Studies or Statistical Data: Medicare Advantage organization may refer to results of studies or statistical data in relation to customer satisfaction, quality, cost, etc. as long as specific study details are given. At a minimum, study details that need to be included are: source, dates, sample size, and number of plans surveyed. Medicare health plans may not use study or statistical data to directly compare their plan to another. If organizations use study data that includes information on several other MA organization, they will not be required to include data on all of the organizations included in the study. However, study details, such as the number of plans included, must be disclosed. Qualified superlatives (e.g., among the best, one of the highest ranked, etc.) may be used. Superlatives (e.g., ranked number one, etc.) may only be used if they are substantiated with supporting data

11. **Benefit and Plan Premium Information:** Pre-enrollment materials that describe benefit and plan premium information must:

- Include the statement: “You must continue to pay your Medicare Part B premium” with premium information, even if the premium is \$0.
- When specifying benefits, specify annual limits (e.g., \$1,000 annual maximum for prescription drugs), annual benefit payout (e.g., \$700 for

eyeglasses every 2 years) and applicable co payments (e.g., \$5 co-payment for a doctor visit).

- Clearly state major exclusions and limitations. For example, restriction of pharmacy benefits to a specific formulary or a restricted set of pharmacies must be explained.
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary's access to drugs or services.
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits, and whether any unused portion of that benefit can be carried over from one calendar quarter to the next.
- Include a closing statement such as: "For full information on [organization name] (e.g., drugs, routine physical exam, eyeglasses, dental, etc.) benefits, call our Customer Service Department at [phone number]. Our office hours are [insert hours]."
- Cost contractors must describe their premiums and cost-sharing for services received through the cost plan, and any optional supplemental benefit packages they offer. They must also indicate that premiums, cost-sharing, and optional supplemental benefits may change each year and include information on when such benefit options may be selected or discontinued
- Make the statement that the Medicare health plan's contract with CMS is renewed annually, and that the availability of coverage beyond the end of the current contract year is not guaranteed.

12. Benefit and Plan Premium Information: Pre-enrollment materials that describe benefit and plan premium information must:

- Include the statement: "You must continue to pay your Medicare Part B premium" with premium information, even if the premium is \$0.
- When specifying benefits, specify annual limits (e.g., \$1,000 annual maximum for prescription drugs), annual benefit payout (e.g., \$700 for eyeglasses every 2 years) and applicable co-payments (e.g., \$5 co payment for a doctor visit).
- Clearly state major exclusions and limitations. For example, restriction of pharmacy benefits to a specific formulary or a restricted set of pharmacies must be explained.

- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary's access to drugs or services.
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits, and whether any unused portion of that benefit can be carried over from one calendar quarter to the next.
- Include a closing statement such as: "For full information on [organization name] (e.g., drugs, routine physical exam, eyeglasses, dental, etc.) benefits, call our Customer Service Department at [phone number]. Our office hours are [insert hours]."
- Cost contractors must describe their premiums and cost-sharing for services received through the HMO or CMP, and any optional supplemental benefit packages they offer. They must also indicate that premiums, cost-sharing, and optional supplemental benefits may change each year.
- Make the statement that the Medicare health plan's contract with CMS is renewed annually, and that the availability of coverage beyond the end of the current contract year is not guaranteed.

B. Formatting Requirements

1. **Font Size Rule for Member Materials:** Readability of written materials is crucial to informed choice for Medicare beneficiaries. All pre-enrollment materials that convey the rights and responsibilities of the Medicare health plan and the member must be printed with a 12-point font size or larger. Materials subject to this requirement include, but are not limited to enrollment and disenrollment forms and notices. The CMS is cognizant of the fact that, when actually measured, 12-point font size may vary among different fonts with the result that some font types may be smaller than others. Times New Roman font type is the standard by which font size is measured. Therefore, if Medicare health plans choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12-point.
2. **Font Size Rule for Materials on the Internet:** Any pre-enrollment materials that a MA organization places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor the Medicare health plan has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the Medicare health plan codes the font for the Web page, not how it actually looks on the user's screen.

3. **Font Size Rule for Footnotes and Subscripts:** The 12-point font size or larger rule described above also applies to any footnotes or subscript annotations in notices.
4. **Footnote Placement:** Medicare health plans must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. For example, the Medicare health plan cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

C. Submission and Review Requirements

1. **Sales Scripts:** Sales scripts, both for in-home and telephone sales use, must be reviewed by the CMS prior to use. However, Medicare health plans are not required to adhere to a specific format for submission (i.e. verbatim text or bullet points).

D. Other Requirements

1. **Logos/Tag Lines:** The CMS recognizes the difference of purpose and intent between company logos/product tag lines and other advertising or marketing materials. The guidelines regarding the use of unsubstantiated statements that apply to advertising materials do not apply to logos/taglines. Contracting health plans may use unsubstantiated statements in their logos and in their product tag lines (e.g., “Your health is our major concern,” “Quality care is our pledge to you,” “First Care means quality care,” etc.). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. Notwithstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., “First Care means the first in quality care” or “Senior’s Plus means the best in managed care”). Refer to the “Must Use/Can’t Use/Can Use” chart in §30.3 of this chapter for more information on restrictions associated with the use of superlatives.

30.3 - “Must Use/Can’t Use/Can Use” Chart

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The “Must Use/Can’t Use/Can Use” Chart provides guidance on language that Medicare health plans must use, can’t use, and can use in pre-enrollment materials and in post-enrollment materials (as addressed in §40.1). With the exception of the “Contract with the Government” topic contained in the Chart, the “Must Use” column does **not** apply to advertisements (as defined in §30.1). Only the “Can’t Use” and “Can Use” column applies to advertisements.

The Chart does not indicate when a particular topic must be included in marketing materials. Instead, it provides guidance on language use when the topic is included on a particular marketing piece. If a topic is required to be included in a marketing material, the requirement for its inclusion can be found in §30.2 for pre-enrollment materials and §40.1 for post-enrollment materials.

Although use of suggested “Can Use” language is not required, its use will expedite the review process. Please note that the specific language and format used in all standardized marketing materials like the standardized Summary of Benefits is required. Please also note that the language provided in the “Must Use” column of the “Must Use/Can’t Use/Can Use Chart” is required if the particular topic is being addressed in a pre- or post-enrollment marketing material.

Some phrases in this document may not apply to your organization’s benefit package or marketing strategy. We caution you to apply the information contained in this document with the understanding that it must be evaluated for applicability to your organization.

“Must Use/Can’t Use/Can Use” Chart

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The following chart provides guidance on language that MA organizations must use, can’t use, and can use in pre-enrollment materials and in post-enrollment materials. With the exception of the “Contract with the Government” topic contained in the Chart, the “Must Use” column does **not** apply to advertisements (as defined in §30.1). Only the “Can’t Use” and “Can Use” column applies to advertisements.

This Chart does not indicate when a particular topic must be included in marketing materials. Instead, it provides guidance on language use when the topic is included on a particular marketing piece. If a topic is required to be included in a marketing material, the requirement for its inclusion can be found in §30.2 for pre-enrollment materials and §40.1 for post-enrollment materials.

The use of any language found in the “Can Use” column is discretionary.

Subject	Must Use	Can’t Use	Can Use	Reason
Lock-In	<ul style="list-style-type: none">- Enrolled members “must use (name of plan/ organization) (contracting, plan, affiliated, or name of plan organization participating) providers for routine care”- “Available to all Medicare beneficiaries”- For Medicare cost plans, all pre-enrollment materials must clearly explain that members may use plan and non-plan providers, and also explain the benefit/cost sharing differentials between use of plan and non-plan providers. <p>This information may be either in the text of the piece or in a disclaimer at the end/bottom of the piece</p>	<ul style="list-style-type: none">- The term “Participating Providers”		

Subject	Must Use	Can't Use	Can Use	Reason
Descriptions of the Medicare health plan's Quality ⁶		<ul style="list-style-type: none"> - Superlatives (e.g., highest, best)⁷ - Unsubstantiated comparisons with other Medicare health plans - Direct negative statements about other Medicare health plans including individual statements from members or former members 	<ul style="list-style-type: none"> - Qualified superlatives (e.g., among the best, some of the highest) - Superlatives (e.g., ranked number 1, if they can be substantiated by ratings, studies or statistics (Source must be identified in the advertising piece.) See §30 for more information. - “[Name of plan/organization] delivers (adjective) quality of care” - Can use satisfaction survey results, e.g., “The (name of specific study) indicated we rated highest in member satisfaction.” (Must disclose year and source.) See §30 for more information. - MA organizations may use CAHPS survey data regarding their own organization but may not use it to make specific comparisons to other MA organizations. 	
Premium Costs	<ul style="list-style-type: none"> - If a Medicare health plan premium is mentioned, it must be accompanied by a statement that beneficiaries must continue to pay Part B premium or Medicare premium. 	<ul style="list-style-type: none"> - “No premium” - “No premium or deductible” - “Free” 	<p>The following may be used:</p> <ul style="list-style-type: none"> - “No plan premium” - “Plan premium equals _____” - “\$0 plan premium” 	

Subject	Must Use	Can't Use	Can Use	Reason
	<p>- If an annual dollar amount/limit is mentioned, quarterly or monthly limits must also be mentioned as well as any ability to carry over any remaining benefit from quarter to quarter.</p>		<p>- At no extra cost to you” but only if referring to a specific benefit</p> <p>- “No plan premium or deductibles”</p> <p>- “No plan premium or deductibles (you must continue to pay the Medicare Part B premium”</p> <p>- “No plan premium beyond your monthly Medicare payment”</p> <p>- “No plan premium other than what you currently pay for Medicare”</p>	
Testimonials	<p>- Content must comply with CMS marketing guidelines, including statements by members.</p> <p>- Speaker must identify specific Medicare health plan membership.</p>	<p>- Cannot have non-members say he/she belongs. (Can use actors, but they cannot say they belong to the Medicare health plan.)</p> <p>- Medicare health plans cannot use negative testimonials about other plans from members or ex-members.</p>		

Subject	Must Use	Can't Use	Can Use	Reason
<p>Contract with the Government</p> <p>Member ID Cards:</p>	<p>With the exception of outdoor advertisements and banner/banner-like ads, the SB, EOC, Member Handbook and all other advertisements and all pre-enrollment materials must include this disclaimer.</p> <p>This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.</p> <ul style="list-style-type: none"> - "A/An [insert plan type: HMO, PPO, POS plan, PSO, etc.] with a Medicare contract" - "An MA organization with a Medicare contract" - "A Health Plan with a Medicare contract" - "A Federally Qualified HMO with a Medicare contract" - "A Federally Qualified Medicare contracting HMO" - "Medicare approved [insert plan type: HMO, PPO, POS plan, PSO etc.]" - "A Coordinated Care Plan with an Medicare Advantage contract" <p><i>In order to facilitate processing of beneficiary inquiries and complaints to CMS and its contractors, all organizations must print their CMS contract</i></p>	<ul style="list-style-type: none"> - "Recommended or endorsed by Medicare" - Cannot imply that Medicare health plan has a unique or custom arrangement with the government, e.g.: -- "Special contract with Medicare" --"Special Medicare health plan for Medicare beneficiaries" 		

Subject	Must Use	Can't Use	Can Use	Reason
	<p><i>number on marketing materials and enrollment card.</i></p> <p><i>H number must print on the front page of Summaries of Benefits and Explanations of Coverage, as well as on enrollment card.</i></p>			
Physicians and Other Health Care Providers	<ul style="list-style-type: none"> - If the number of physicians and other health care providers is used, it must include only providers available to Medicare beneficiaries. - If a total number of physicians and providers is used it must separately delineate the number of primary care providers and specialists included. - If the Medicare health plan uses the name and/or picture of providers and/or facilities to market itself, the provider information may only be used within the context of informing beneficiaries of providers that are associated with the organization's delivery system. 	<ul style="list-style-type: none"> - Implication that providers are available exclusively through the particular HMO unless such a statement is true - "Participating providers" unless you use Medicare health plan name - The MA organization may not identify itself by the name of a participating provider or provider group, with the exception of a PSO. 	<ul style="list-style-type: none"> - "(Medicare health plan's name) participating providers" - "Plan" providers - "Network" providers - "Contracting" providers - "Affiliated" providers - Number of providers should be same total number of Medicare providers 	<p>Do not use the word "participating" when referring to Medicare health plan providers (unless you use Medicare health plan name), since it could be confused with a participation agreement with Medicare. Organizations should either use "contracting" or "Medicare health plan name" when referring to Medicare health plan providers.</p> <p>It must be clear to the beneficiary with whom the contract with CMS is held.</p>
Eligibility	<ul style="list-style-type: none"> - Must indicate that beneficiaries must be entitled to Part A and enrolled in B For MA plans-- Must indicate that 	<p>"No health screening" unless specific mention is made of ESRD</p> <p>"Seniors" unless term</p>	<ul style="list-style-type: none"> - "Anyone with Medicare may apply" - "Medicare entitled by age or disability" 	<p>Since all Medicare beneficiaries may enroll in Medicare-contracting HMOs, you may not refer to your plan as a "senior Medicare health plan" (unless you</p>

Subject	Must Use	Can't Use	Can Use	Reason
	<p>all Medicare beneficiaries with Parts A and B of Medicare may apply</p> <p>For §1876 cost contracting health plans:</p> <p>-- Must indicate that all Medicare beneficiaries may apply (This requirement doesn't apply to MA Special Needs Plan)</p> <p>This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.</p>	<p>appears with “and all other Medicare eligibles”</p> <p>“[Name of Medicare Health plan] designed especially for seniors”</p> <p>“Senior Medicare health plan” unless part of Medicare health plan name</p> <p>“Individuals age 65 and over”</p>	<p>- “Individuals eligible for Medicare by age or disability”</p> <p>- “Individuals on or entitled to Medicare by age or disability”</p> <p>- “Medicare beneficiaries”</p> <p>- “Medicare enrollees”</p> <p>- “People with or on Medicare”</p> <p>- “No physicals required”</p> <p>- “No health screening” if a caveat is included for ESRD</p> <p>- “Grandfathered enrollees” - “People who meet specific enrollment criteria” (SNP only)</p> <p>-“Individuals who meet the definitions of a special needs” (SNP only)</p> <p>-“All dual eligible Medicare beneficiaries” (SNP only)</p> <p>-“All Institutionalized Medicare beneficiaries” (SNP only)</p>	<p>refer to it as part of the health plan name). The term “senior Medicare health plan” implies that disabled beneficiaries may not enroll.</p> <p>Medicare Part A is not a requirement for enrollment in Medicare-cost contracting HMOs. MA organizations may only enroll individuals with both Parts A and B of Medicare, with the exception of “grandfathered” members.</p>

Subject	Must Use	Can't Use	Can Use	Reason
Claims Forms / Paperwork		<p>“No paperwork”</p> <p>“No claims or paperwork/complicated paperwork”</p> <p>No claims forms”</p>	<p>“Virtually no paperwork”</p> <p>“No paperwork when using Medicare health plan providers”</p> <p>“Hardly any paperwork”</p>	Members may be required to submit bills or claims documentation when using out-of-plan providers.
Benefits: a) Comparison	<p>- If premiums and benefits vary by geographic area, must clearly state this or must clearly state geographic area in which differing premiums and benefits are applicable.</p> <p>- If only benefits vary, clearly state geographic areas in which benefits are applicable.</p>	<p>- Minimal co-pays may vary by county</p> <p>- Minimal co-pays may apply</p>	<p>- “Premiums and benefits may vary by county [and plan]” or “These benefits apply to the following counties”*</p> <p>- “Except for _____ county”*</p> <p>- Medicare health plans may compare benefits to Medigap plans as long as information is provided accurately and in detail.</p>	Premiums, benefits, and/or co-payment amounts may vary by county within a given service area.
Benefits: b) Limitations		<p>- “At no extra cost to you” or “free” if co-pays apply</p>	<p>- State exact dollar amount limit on any benefit</p> <p>- “Limitations and restrictions may apply”</p> <p>- “Minimal co payments will apply”</p> <p>- “Minimal co-payments vary by county”*</p> <p>- State which benefits are subject to limitations</p>	If benefits are specified within the piece, any applicable co-payment should be stated or you may include the general statement as shown.

Subject	Must Use	Can't Use	Can Use	Reason
<p>Benefits:</p> <p>c) Prescription Drugs</p>	<ul style="list-style-type: none"> - If prescription drugs are mentioned and have limitations, must say: - Limited outpatient drug coverage; or, - Drug coverage benefits subject to limitations; or - Up to xxx annual/ quarterly/ monthly limit or xxx limit per year/quarter/month and other limits and restrictions may apply. - Co-payment amounts and indicate for a xx number of days supply - If benefits are restricted to a formulary, this must be clearly stated. - In addition, must state: - That formulary contents are subject to change within a contract year without advance notice - Medicare health plan should be contacted for additional details. 	<ul style="list-style-type: none"> - “We cover prescription drugs” unless accompanied by reference to limitation - “Prescription drug coverage” unless accompanied by reference to limitation 	<ul style="list-style-type: none"> - Fully disclose dollar amount of co-payments and annual/quarterly/monthly limit - If limited, you must say so - Limited outpatient drug coverage with xx co-payments for xx number of days supply and xxx annual/quarterly/monthly limit - “Prescriptions must be filled at contracting or Medicare health plan affiliated pharmacies.” 	<p>Prescription drugs are an important benefit that must be adequately described. Any dollar limits must be clearly conveyed.</p>

Subject	Must Use	Can't Use	Can Use	Reason
Benefits: d) Multi-Year Benefits	- Whenever multi-year benefits are discussed, MA organizations are required to make appropriate disclosure that the benefit may not be available in subsequent years.		- “[benefit] may not be available in subsequent years” OR - “[name of MA organization] contracts with Medicare each year, this benefit may not may not be available next year” - “At the end of each year, [name of organization] may leave the Medicare program or change plan benefits. However, new plans or benefits may also become available.”	Potential applicants and members must be informed that multi-year benefits in current year benefit packages are not guaranteed in future contract years.
e) <i>Internet web page</i>	<i>For the EOC and the SB, the organization will provide marketing materials via an Internet Web page, and must establish a process to inform members when that Web page has been updated. For example, the organization could notify members by newsletter article, by e-mail, by postcard, etc. Often any change in the EOC or SB is communicated to all members by newsletter and notification that the change has been made on the Web page. Provider directories must also be posted to the MA organization website. All internet marketing pages being used</i>			

Subject	Must Use	Can't Use	Can Use	Reason
	<i>must display the Plan's Contract Number, approved Marketing Identification Number, and the date (month/year) of the CMS approval notice. This information must be displayed in the lower left or right corner of the internet page or document</i>			
- Definitions - Emergency and Urgently Needed Care		- "Life threatening" - "True emergency"	- Emergency - definition as stated in current CMS policy. - Urgent - definition as stated in current CMS policy.	Emergency and urgent care criteria should be explained per Medicare guidelines rather than in the commercial context.
Drawings / Prizes		- "Eligible for free drawing and prizes"	- "Eligible for a free drawing and prizes with no obligation" - "Free drawing without obligation"	It is a prohibited marketing practice to use free gifts and prizes as an inducement to enroll. Any gratuity must be made available to all participants regardless of enrollment. The value of any gift must be less than the nominal amount of \$15.
Sales presentations	- Indicate that a telecommunication device for the deaf (TTY) is available to get additional information or to set up a meeting with a sales representative.		"A telecommunications device for the deaf (TTY) is available to get additional information or set up a meeting with a sales representative."	

Subject	Must Use	Can't Use	Can Use	Reason
	<p>If mentioned in a response card where the beneficiary's phone number is requested:</p> <ul style="list-style-type: none"> - "A sales representative may call." 	<ul style="list-style-type: none"> - "A health plan representative will be available to answer questions." 		
<p><i>Medicare Advantage Provider Sponsored Organizations</i></p>	<p><i>Must provide 70 % of Medicare covered services directly to MA Plan enrollees in urban areas; and for rural PSO, at least 60% (ref 422.354)</i></p>	<ul style="list-style-type: none"> - State licensed MA organizations may not use the specific term "MA PSO" or imply that they are one of the specific PSO options for Medicare beneficiaries defined by the Balanced Budget Act of 1997 and implementing regulations at 42 CFR 422.350-.356. 	<ul style="list-style-type: none"> - May only identify itself as an "MA Provider Sponsored Organization (PSO)" or imply that it is one of the PSO options for Medicare beneficiaries under MA if it has received a State licensure waiver from CMS in accordance with 42 CFR 422.370-.378. - State licensed MA organizations may identify themselves as a "Provider Sponsored Organization (PSO)," a "State licensed PSO with a MA contract," or any other term generally applied to managed care organizations that are sponsored by health care providers 	

⁶ Note - CMS has the discretion to disapprove language based on site visit reviews identifying substantial deficiencies in Medicare health plan operations.

⁷ Note - A member of the organization may use a superlative in relating their personal experience with the organization so long as the testimonial is preceded with the phrase “in my opinion” (e.g., “I have been with the plan/organization for 10 years and in my opinion they have given me the best care possible.”) If the member does not preface the superlative statement with the “in my opinion” phrase, the member must substantiate the statement with an acceptable qualifying information source.

DRAFT

40 - Guidelines for Post-Enrollment Materials

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

“Post-enrollment” materials are those materials used by Medicare health plans to convey benefit or plan operational information to enrolled beneficiary health plan members. Post-enrollment marketing materials includes all notification forms and letters and sections of newsletters that are used to enroll, disenroll, and communicate with the member on many different membership operational policies, rules and procedures. Post-enrollment marketing materials include, but are not limited to, the Annual Notice of Change, the Evidence of Coverage, the Provider Directory, and the Summary of Benefits. These materials are also called beneficiary notification materials and subject to additional CMS requirements.

This section is organized in several sub-sections:

- 40.1 -- provides guidelines on beneficiary notification materials
- 40.2 -- provides guidelines on provider directories
- 40.3 -- provides guidance on drug formularies
- 40.4 -- provides guidelines on outreach to dual eligible membership
- 40.5 -- provides guidance on the SB
- 40.6 – *provides guidance on the EOC*

Please note that Medicare health plans may not use Medicare member lists for non-plan-specific purposes. If an organization has questions regarding specific material, which it wishes to send to its Medicare members, the material should be submitted to CMS for a decision.

NOTE: The requirements outlined in the “Must Use/Can’t Use/Can Use” Chart contained in §30.3 also apply to post-enrollment materials.

40.1 - General Guidance for Post-Enrollment Materials

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

In many cases, the requirements for pre-enrollment notices (in §30) are the same for post-enrollment materials. The following are guidelines for post-enrollment materials:

A. Language Requirements

1. **Lock-In Statement:** The concept of “lock-in” must be clearly explained in the SB, the EOC, and Member Handbooks.

For Medicare cost plans, all pre-enrollment materials must clearly explain that members may use plan and non-plan providers, and also explain the benefit/cost sharing differentials between use of plan and non-plan providers.
2. **Networks and Sub-networks:** The SB, the EOC, Provider Directories and Member Handbooks must clearly explain the concept of networks and sub-networks and the process for obtaining services including referral requirements.
3. **Hours of Operation:** Medicare health plans must list the hours of operation for customer services and other health plan services anywhere that these phone numbers are provided. This includes listing the hours of operation for 1-800-MEDICARE any time the organization lists the 1-800-MEDICARE number (24 hours a day/7 days a week).
4. **Contracting Statement:** The SB, Member Handbooks, and the EOC must include a statement that the organization contracts with the Federal government. Refer to the Must Use/Can’t Use/Can Use chart in §30. for statements the organization may use. All other post enrollment materials are not required to have this statement (i.e., it is optional).
5. **TTY Numbers:** TTY numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. The TTY number must also include the hours of operation, if they are for customer or health plan services. Medicare health plans can use either their own or State relay services, as long as the number included is accessible from TTY equipment.
6. **Availability of Alternative Formats (EOC only):** To ensure that beneficiaries have access to beneficiary education materials in alternative formats (e.g. Braille, foreign languages, audio tapes, large print), Medicare health plans must provide a disclosure on the EOC indicating the document is available in alternative formats.
7. **Reference to Studies or Statistical Data:** Medicare Health plans may refer to results of studies or statistical data in relation to customer satisfaction, quality, cost, etc. as long as specific study details are given. At a minimum, study details

that need to be included are: source, dates, sample size, and number of plans surveyed. Organizations may not use study or statistical data to directly compare their plan to another. If Medicare health plans use study data that includes information on several other Medicare health plans, they will not be required to include data on all of the organizations included in the study. However, study details, such as the number of plans included, must be disclosed. Qualified superlatives (e.g., among the best, one of the highest ranked, etc.) may be used. Superlatives (e.g., ranked number one, etc.) may only be used if they are substantiated with supporting data.

- 8. Member ID Cards:** CMS recommends that all Medicare health plans, especially PPOs and PFFS Plans, include the phrase “Medicare limiting charges apply” on Member ID cards. However, use of this phrase is optional. The CMS believes that use of this phrase on a card that most providers will see is a reliable method of informing providers of the billing rules for the plan, and thus could reduce the chance for incorrect or inappropriate balance billing.

The CMS also recommends that PPOs and PFFS Plans include the statement that the provider should bill the PPO or PFFS organization and not Original Medicare. The CMS believes this statement will help prevent claim processing errors. However, use of this statement is optional.

- 9. In order to facilitate processing of beneficiary inquiries and complaints to CMS and its contractors, all organizations must print their CMS contract number on marketing materials and enrollment card. At a minimum, the H number will need to be printed on the front page of Summaries of Benefits and Explanations of Coverage, as well as on enrollment card.*

10. Preferred Provider Organizations (including PPO Demonstrations) Only:

- **Mandatory Supplemental Benefits:** If a PPO offers benefits, including mandatory supplemental benefits (such as prescription drugs or dental services) that are limited to in-network providers and facilities, marketing materials that mention these benefits must state that not all benefits are available from non-preferred providers. The EOC must specifically explain which benefits are offered at the non-preferred benefit level and any limitations that may apply.
- **Prior Notification/Authorization Requirements:** Some PPOs may require or request that members notify them prior to receiving certain services. In these cases, the organization must clearly define the requirement in marketing materials. It must also include the information in the PBP Notes section so that the appropriate language regarding the penalty may be used in marketing materials. If there is a penalty for not receiving prior referral/notification/authorization, marketing materials that mention these services must clearly describe the penalty.

- **Post-Stabilization (PPO Demonstrations Only):** In the EOC and the SB (Section 3), PPO Demonstrations must specify all cost sharing requirements with regard to emergency hospital admissions, including whether the in-network or out-of-network cost sharing is required for enrollees who are stabilized and receive post-stabilization care in a non-preferred (out-of-network) hospital following an emergency situation. If the Demo includes a cap on enrollee out-of-pocket costs for such services, state the out-of-pocket maximum amount. In the EOC, clearly state any other requirements associated with an out-of-network emergency hospital admission, e.g., enrollee notification upon stabilization, policies with regard to transfers to network hospitals, etc.

B. Formatting Requirements

1. **Font Size Rule for Member Materials:** Readability of written materials is crucial to informed choice for Medicare beneficiaries. All member materials that convey the rights and responsibilities of the Medicare health plan and the member must be printed with a 12-point font size or larger. Materials subject to this requirement include, but are not limited to, the EOC or member brochure and contract, letters confirming enrollment and disenrollment, notices of non-coverage and notices informing members of their right to an appeals process. The CMS is cognizant of the fact that, when actually measured, 12-point font size may vary among different fonts with the result that some font types may be smaller than others. Times New Roman font type is the standard by which font size is measured. Therefore, if Medicare health plans choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12-point.

Exception:

- Due to the size of the member ID card, the member ID card need not have all information in a 12-point font size or larger.
2. **Font Size Rule for Internet Materials:** Unless an exception for font size is noted in #1 above, any post-enrollment materials that a Medicare health plan places on its Web site need to be in a minimum 12-point Times New Roman-equivalent font. Neither CMS nor organization has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user. Therefore, the 12-point font requirement refers to how the organization codes the font for the Web page, not how it actually looks on the user's screen.
 3. **Font Size Rule for Footnotes and Subscripts:** The 12-point font size or larger rule also applies to any footnotes or subscript annotations in post-enrollment notices.

4. **Footnote Placement:** Medicare health plans must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. For example, the organization cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

C. Other Requirements

1. **Media Type:** *With respect to the SB, the EOC, and the Provider Directory, MA organizations have the option of contacting members to determine in what format they would like to receive the materials (e.g., hardcopy, CD ROM, MA organizations that choose this option must contact members in writing (e.g., by letter, postcard, newsletter article, etc.) to determine whether they would like to receive the SB, EOC, and/or the Provider Directory in another format. If the organization does not receive a response from the member, then the organization must assume that the member wants to receive the information in hardcopy.*

If the organization sends one provider directory to an address where up to four members reside (as allowed in §40.2), then it may send one written notice regarding choice of media type to that address (if it is notifying members by letter), rather than one notice to each individual member at that address. A reply from one member at that address constitutes a reply for the entire address.

The following would also apply:

- The member must receive the materials in the required time frames, regardless of the format.
- For the EOC and the SB, the organization will provide marketing materials via an Internet Web page, and must establish a process to inform members when that Web page has been updated. For example, the organization could notify members by newsletter article, by e-mail, by postcard, etc. Often any change in the EOC or SB is communicated to all members by newsletter and notification that the change has been made on the Web page could be made at the same time. This requirement does not apply to provider directories since provider directories since provider directory updates can occur far more frequently than updates to the EOC or SB.
- The non-hardcopy format should match the approved hardcopy format, and if it does, it will not need additional CMS approval. If anything is added or deleted, the non-hardcopy format must receive separate CMS approval.

NOTE: Some organizations use a database/search function for their provider directory on the Internet. In this case, as long as the information that comes up on a specific provider is the same information as what is contained in the hardcopy format, then the Internet provider directory would be considered to be the same as the hardcopy format and would not need additional CMS approval.

40.1.1 - Use of Model Post-Enrollment Materials

(Rev. 35, 10-31-03)

The passage of the Benefits Improvement and Protection Act of 2000 has changed the review process for model beneficiary notification materials. For specific guidance on These changes and the usage of model materials, see §20, "Marketing Review Process."

40.1.2 - Use of Standardized Post-Enrollment Materials

(Rev. 42, 01-09-04)

The CMS has implemented certain standardized beneficiary notification marketing materials for health plan participants in Medicare managed care. In particular, all MA organizations are required to use a standardized Summary of Benefits (SB). Use of standardized materials by MA organizations is mandatory. Guidelines for the standard SB can be found in §40.4.

The MA organizations must send an SB to members of employer group plans and to members of individual plans who have joined the individual plan through their employer, or it must arrange to have the employer send one to these members. However, MA organizations are exempt from using the **standardized** SB for employer group members and members of individual plans who have joined the individual plan through their employer, and may instead develop a different format for the SB.

40.1.3 - Model Annual Notice of Change

(Rev. 35, 10-31-03)

*All MA organizations are required to give members the annual notice of the change of Medicare program and health plan changes taking place each year on January 1 of the upcoming year. The organizations must ensure that members receive this Annual Notice 15 days prior to Annual Coordinated Election Period Annual (AEP). The AEP for 2006 is Nov. 15th, 2005 - May 15th, 2006. In 2007 and beyond, Nov. 15th - Dec. 31st. Cost plans must give notice within 30 days of the effective date of the Medicare program and health plan changes (i.e., by December 1 for January 1 changes). This requirement applies to all plan enrollees, including employer group enrollees. "Give notice" means that members must have **received** the notice by the required date. This notice is known as the "Annual Notice of Change," or "ANOC."*

The ANOC must be member specific. This means that the notice must have the member's own name either on the envelope addressed to the member or on the ANOC itself. The following is a model ANOC for MA organizations and cost plans.

NOTE: Regarding ANOCs and SBs for employer group members: With one exception, health plans/MA organizations must send ANOCs and SBs to employer group members at the same time they send it to all other individual members. The exception is when there are no Medicare changes **or** plan changes taking effect on January 1 of the upcoming year. In this case, the organization does not need to send an ANOC (or an SB) to employer group enrollees. For example, if there were no January 1 changes in Medicare coverage to communicate to enrollees in a particular year, it is possible that an organization may not have any January 1 plan changes to communicate to their employer group enrollees if the employer group open enrollment season occurs at some other time during the year (e.g., July 1). Under these circumstances, the organization does not need to send an ANOC (or an SB) to employer group members in October (or December for Medicare cost plans). However, keep in mind that the organization would still need to notify employer group enrollees of any upcoming plan changes with an ANOC and SB at least 30 days in advance of those changes, as required at 42 CFR 422.111(d)(3) and 42 CFR 417.436(c).

*** Note-For CY 2006 CMS has developed three model ANOC's**

**MODEL ANNUAL NOTICE OF CHANGE
MA-only**

Dear *[member name]* - or - *[Member]*:

[Note: The organization may modify this introductory paragraph to tailor to its needs, as long as the paragraph is kept brief.] This is the time of year when we like to thank you for your membership and inform you of new plan changes for the upcoming year. Beginning January 1, 2006, there will be some changes to *[insert plan name]*. The following changes are described in this letter.

- **The new Medicare Prescription Drug Coverage**
- **How will my monthly premiums change?**
- **How will my benefits and costs change?**
- **Are there other benefits I can get? *[insert if applicable]***
- **What changes affect when I join or leave Medicare health plans?**

The new Medicare Prescription Drug Coverage

Beginning January 1, 2006, new Medicare prescription drug coverage will be available to all people with Medicare. *[Name of plan]*, the plan you are enrolled in, does **not** include

this prescription drug coverage. If you are interested in enrolling in this new Medicare prescription drug coverage, you can get it through the following plans offered by our organization:

[List name of plans & member services contact]

To join one of these plans that are offering the new Medicare Prescription Drug coverage, contact the Member Services provided above. If you enroll in another Medicare Health Plan or Medicare prescription drug plan, you will be disenrolled from [name of plan] when your enrollment in the new plan begins.

If you do not enroll in a plan that offers Medicare prescription drug coverage or a Medicare Prescription Drug plan by May 15, 2006, you may have to pay a higher premium.

How will my monthly premiums change?

Starting January 1, 2006, the monthly premium that you pay to [insert plan name] will [increase/decrease] from \$_____ to \$_____ OR stay the same at \$_____.

How will my benefits and costs change?

[Clearly describe all other benefit changes, including changes in cost sharing and any new benefits that will be offered by the plan in the coming year or that will be covered by Medicare. Also describe any benefits offered in the current year that will no longer be offered by the plan in the upcoming year, this includes any drug coverage that will no longer be covered. When describing benefit changes, do so by comparing the current year benefit with the upcoming year benefit.]

We have enclosed a summary of your benefits, premiums and copays that will be effective January 1, 2006. Medicare has reviewed and approved the changes in benefits, premiums, and other costs included in this letter and on the enclosed Summary of Benefits. We will send you an [insert: "Evidence of Coverage" or whichever name you use as the name for the EOC] [insert either "by [date]" or "at a later date"]. All changes begin January 1, 2006, and will be in effect through December 31, 2006. Rest assured that you will be a member of [insert plan name] for the coming year if you do nothing to change your Medicare coverage.

[If the organization lists more than one plan offering on the enclosed SB, the organization must identify the specific plan in which the member will be enrolled. In addition, if the organization lists only one plan in the SB but offers multiple plans in the service area, the ANOC must notify beneficiaries that additional plans are available and include specific information on how beneficiaries can obtain more information.]

Are there other benefits I can get?

[Include this section if the plan offers optional supplemental benefits.]

[Clearly describe any optional supplemental benefits and the premiums for those benefits. A description of the process that the member must follow to elect optional supplemental benefits must also be included.]

What changes affect when I can join or leave Medicare health plans?

Starting in 2006, there are some limits to when and how often you can change the way you get Medicare and what choices you can make when you make the change. Switching from one MA plan (like [name of plan]) to one of the other MA plans we offer, counts towards making a change.

1. **From November 15, 2005 through May 15, 2006**, anyone with Medicare has opportunities to switch from one way of getting Medicare to another.
2. **From January 1, 2006 until June 30, 2006**, anyone with Medicare (including members of [Plan Name]) has an additional opportunity to make a change in the way they get Medicare.

During this time, you are limited in the type of plan you may join. When making your one change, you may only choose to join a Medicare managed care plan or Medicare Private Fee-for-Service plan that does not offer the Medicare Prescription Drug coverage, or to choose Original Medicare.

3. Generally, you may not make any other changes during the year unless you meet certain special exceptions, such as if you move or if you have Medicaid coverage. Later in the year, **from November 15 through December 31**, anyone with Medicare can switch from one way of getting Medicare to another for the following year.

Where can I get more information?

Please call our Member Services Department [insert days and hours of operation], at [insert phone number] if you have any questions. TTY users should call [insert TTY phone number].

You can contact us if you need additional information, including:

- Information about how we control the use of services and costs;

[Cost plans do not need to include the remaining three bullets]

- Information on the number of appeals and grievances filed by our members;

- A summary description of how we pay our doctors;
- A description of our financial condition, including a summary of our most recently audited statement.

You can also get information about the Medicare program and Medicare health plans from www.medicare.gov on the web or by calling 1-800 MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. Medicare customer service representatives are available, 24 hours a day, including weekends, to answer questions about Medicare.

We look forward to serving you now and in the future.

Sincerely,

Plan Representative

MODEL ANNUAL NOTICE OF CHANGE MA-PD

Dear [member name] - or - [Member]:

[Note: The organization may modify this introductory paragraph to tailor to its needs, as long as the paragraph is kept brief.] This is the time of year when we like to thank you for your membership and inform you of new plan changes for the upcoming year. Beginning January 1, 2006, there will be some changes to [insert plan name]. These following changes are described in this letter:

- **The new Medicare prescription drug coverage**
- How will my monthly premiums change?
- **How will my “other” benefits and costs change?**
- **Are there other benefits I can get?** [insert if applicable]
- **What changes affect when I can join or leave Medicare health plans?**
- **If I have Medicaid drug coverage, can I keep it?**

The new Medicare Prescription Drug Benefit

Beginning January 1, 2006, new Medicare prescription drug coverage will be available to all people with Medicare. We are pleased to announce that [Name of Plan] will include Medicare prescription drug coverage beginning January 1, 2006. Because you are a member of [Name of Plan], you automatically have Medicare prescription drug coverage from [Name of Plan]. The following describes how our prescription drug benefit will change beginning in January.

[Clearly describe how your new Medicare Part D coverage changes from your prior year drug coverage, including changes in cost sharing, annual drug cap, and drug coverage.]

Also describe any drug coverage offered in the current year that will no longer be offered by the plan in the upcoming year. If you offered a Medicare-approved drug discount card, also explain that this card will no longer be available. When describing changes, do so by comparing the current year benefit with the upcoming year benefit.]

How will my monthly premiums change?

Starting January 1, 2006, the monthly premium that you pay to [insert plan name] will [increase/decrease] from \$____ to \$____ OR stay the same at \$____. [MA-PD Plans include the following sentence.] This monthly premium includes your Medicare Prescription Drug coverage (see “The New Medicare Prescription Drug Coverage” above). If you have a limited income and resources, and you qualify for extra help with your Medicare prescription drug costs, your total monthly premium **may decrease by as much as** [insert regional **benchmark premium** amount].

How will my “other” benefits and costs change?

In addition to the Medicare Prescription Drug coverage that will be a part of your plan, the following changes will occur in your coverage.*[Clearly describe all other benefit changes, including changes in cost sharing and any new benefits that will be offered by the plan in the coming year or that will be covered by Medicare. Also describe any benefits offered in the current year that will no longer be offered by the plan in the upcoming year. If you offered a Medicare-approved drug discount card, also explain that this card will no longer be available. When describing benefit changes, do so by comparing the current year benefit with the upcoming year benefit.]*

We have enclosed a summary of your benefits, premiums and co-payments that will be effective January 1, 2006. Medicare has reviewed and approved the changes in benefits, premiums, and other costs included in this letter and on the enclosed Summary of Benefits. We will send you an *[insert: “Evidence of Coverage” or whichever name you use as the name for the EOC]* *[insert either “by [date]” or “at a later date”]*. All changes begin January 1, 2006, and will be in effect through December 31, 2006. Rest assured that you will be a member of [insert plan name] for the coming year if you do nothing to change your Medicare coverage.

[If the organization lists more than one plan offering on the enclosed SB, the organization must identify the specific plan in which the member will be enrolled. In addition, if the organization lists only one plan in the SB but offers multiple plans in the service area, the ANOC must notify beneficiaries that additional plans are available and include specific information on how beneficiaries can obtain more information.]

Are there other benefits I can get?

[Include this section if the plan offers optional supplemental benefits.]

[Clearly describe any optional supplemental benefits and the premiums for those benefits. A description of the process that the member must follow to elect optional supplemental benefits must also be included.]

DRAFT

What changes affect when I can join or leave Medicare health plans?

Starting in 2006, there are some limits to when and how often you can change the way you get Medicare and what choices you can make when you make the change. Switching from one MA plan (like *[name of plan]*) to one of the other MA plans that we offer, counts towards making a change.

1. **From November 15, 2005 through May 15, 2006**, anyone with Medicare will have opportunities to switch from one way of getting Medicare to another.
- 2 **From January 1, 2006 until June 30, 2006**, anyone with Medicare (including members of [Plan Name]) has an additional opportunity to to make a change in the way they get Medicare.

During this time, you are limited in the type of plan you may join. When making your one change, you may only choose to join a Medicare managed care plan or Medicare Private Fee-for-Service plan that offers the Medicare Prescription Drug coverage, or to choose Original Medicare and join a Prescription Drug Plan.

3. Generally, you may not make any other changes during the year unless you meet certain special exceptions, such as if you move out of the plan's service area or if you have Medicaid coverage. Later in the year, **from November 15 through December 31**, anyone with Medicare can switch from one way of getting Medicare to another for the following year.

Note: If you enroll in another Medicare plan, including a Medicare prescription drug plan, you will be disenrolled from our plan when your enrollment in the new plan begins.

If I have Medicaid drug coverage, can I keep it?

No. Federal law will not let Medicaid continue the drug coverage you currently get. Some state Medicaid programs may cover those prescriptions that won't be covered by Medicare prescription drug coverage. However, this coverage alone won't be at least as good as Medicare prescription drug coverage. For complete coverage, you still need Medicare prescription drug coverage.

Where can I get more information?

Please call our Member Services Department [insert days and hours of operation], at [insert phone number] if you have any questions. TTY users should call [insert TTY phone number].

You can contact us if you need additional information, including:

- Information about how we control the use of services and costs;

[Cost plans do not need to include the remaining three bullets]

- Information on the number of appeals and grievances filed by our members;
- A summary description of how we pay our doctors;
- A description of our financial condition, including a summary of our most recently audited statement.

You can also get information about the Medicare program and Medicare health plans from www.medicare.gov on the web or by calling 1-800 MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. Medicare customer service representatives are available, 24 hours a day, including weekends, to answer questions about Medicare.

We look forward to serving you now and in the future.

Sincerely,

Plan Representative

MODEL ANNUAL NOTICE OF CHANGE

For full-benefit dual eligible enrollees of MA-only plans for whom the plan will facilitate their enrollment into an MA-PD plan offered by their parent organization effective 1/1/2006

Dear [member name] - or - [Member]:

[Note: The organization may modify this introductory paragraph to tailor to its needs, as long as the paragraph is kept brief.] This is the time of year when we like to thank you for your membership and inform you of new plan changes for the upcoming year. Beginning January 1, 2006, there will be some changes to [insert plan name]. The following changes are described in this letter.

- **How you get your prescription drug coverage is changing - Important!**
- **How will my monthly premiums change?**
- **How will my benefits and costs change?**
- **Are there other benefits I can get? [insert if applicable]**
- **What changes affect when I join or leave Medicare health plans?**

How you get your prescription drug coverage is changing

Starting January 1, 2006, Medicare will help pay for your drugs. This means Medicaid will stop paying for your prescription drugs after December 31, 2005. [Insert MA-only name] will not be offering Medicare drug coverage next year. To make sure that you don't lose a day of prescription drug coverage, we are going to enroll you in [insert MA-PD plan name]. We will start paying for your prescription drugs on January 1, 2006. If you don't want [insert MA-PD plan name], then you need to call us at 1-XXX-XXX-XXXX by December 31, 2005. Medicaid will still pay for your other medical costs. You will pay a small co-payment [insert amount only if plan is able to give exact \$ amount] for each prescription.

How will my monthly premiums change?

Starting January 1, 2006, the monthly premium that you pay to [insert MA-PD name] will [increase/decrease] from \$____ to \$____ OR stay the same at \$____. [

How will my benefits and costs change?

[Clearly describe all other benefit changes, including changes in cost sharing and any new benefits that will be offered by the plan in the coming year or that will be covered by Medicare. Also describe any benefits offered in the current year that will no longer be offered by the plan in the upcoming year, this includes any drug coverage that will no longer be covered. When describing benefit changes, do so by comparing the current year benefit with the upcoming year benefit.]

We have enclosed a summary of your benefits, premiums and co-payments that will be effective January 1, 2006. Medicare has reviewed and approved the changes in benefits, premiums, and other costs included in this letter and on the enclosed Summary of Benefits. We will send you an [insert: "Evidence of Coverage" or whichever name you use as the name for the EOC] [insert either "by [date]" or "at a later date"]. All changes begin January 1, 2006, and will be in effect through December 31, 2006. Rest assured that you will be a member of [insert plan name] for the coming year if you do nothing to change your Medicare coverage.

[If the organization lists more than one plan offering on the enclosed SB, the organization must identify the specific plan in which the member will be enrolled. In addition, if the organization lists only one plan in the SB but offers multiple plans in the service area, the ANOC must notify beneficiaries that additional plans are available and include specific information on how beneficiaries can obtain more information.]

Are there other benefits I can get?

[Include this section if the plan offers optional supplemental benefits.]

[Clearly describe any optional supplemental benefits and the premiums for those benefits. A description of the process that the member must follow to elect optional supplemental benefits must also be included.]

What can I join or leave my Medicare health plan?

Because you have Medicare and Medicaid, you can change to another health plan at any time. Other people with Medicare can choose to leave their Medicare health plans from November 15 through December 31 of every year and in certain other cases, such as if they move or enter a nursing home.

Can I keep my Medicaid drug coverage?

No. Federal law will not let Medicaid continue the drug coverage you currently get. Some state Medicaid programs may cover those prescriptions that won't be covered by Medicare prescription drug coverage. However, this coverage alone won't be at least as good as Medicare prescription drug coverage. For complete coverage, you still need Medicare prescription drug coverage.

What if I don't want Medicare prescription drug coverage?

If you don't want to join [insert MA-PD plan], and you don't want us to enroll you in a Medicare prescription drug plan, you must call [insert member service phone number] and tell us. If you 1) decide not to enroll, and 2) don't have other drug coverage that is at least as good as Medicare prescription drug coverage, you may have to pay more for Medicare prescription drug coverage after May 15, 2006. You can change your mind and enroll in a Medicare prescription drug plan at any time, but you may have to pay a higher premium for your drug coverage.

Where can I get more information?

Please call our Member Services Department [insert days and hours of operation], at [insert phone number] if you have any questions. TTY users should call [insert TTY phone number].

You can contact us if you need additional information, including:

- Information about how we control the use of services and costs;

[Cost plans do not need to include the remaining three bullets]

- Information on the number of appeals and grievances filed by our members;
- A summary description of how we pay our doctors;

- A description of our financial condition, including a summary of our most recently audited statement.

You can also get information about the Medicare program and Medicare health plans from www.medicare.gov on the web or by calling 1-800 MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. Medicare customer service representatives are available, 24 hours a day, including weekends, to answer questions about Medicare.

We look forward to serving you now and in the future.

Sincerely,

Plan Representative

40.2 - Specific Guidance About Provider Directories

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

Regulations at 42 CFR 422.111(a) and (b) require that MA organizations disclose the following information to each enrollee in clear, accurate, and standardized form at the time of enrollment and at least annually thereafter.⁹ MA organizations usually include this information in their provider directory. The directory is then given to new members upon enrollment and existing members on an annual basis.¹⁰ Regulations at 42 CFR 417.436(a)(2) and (b) also require that Medicare cost plans send a provider directory to members at the time of enrollment and annually.

The directory must include:

1. The number, mix, and distribution, including addresses of providers from whom enrollees may obtain services, as well as any out-of-network coverage or point-of-service option.

In addition, provider directories should also contain the following (this is optional):

1. Names, complete addresses, and phone numbers of the primary care physicians;
2. Names and addresses (city or town) of specialists, skilled nursing facilities, hospitals, outpatient mental health providers, and pharmacies, where outpatient prescription drugs are offered by the MA plan;
3. General information regarding lock-in, including the role of the primary care physician (PCP) as well as the process for selecting a new PCP and any specific requirements for referrals to specialists and ancillary providers;

4. A description of the plan's service area, including a list of cities and towns;
5. Telephone numbers for customer service or appropriate contact information (including the hours of service) for members who have questions or require assistance in selecting a PCP; ¹¹
6. Instructions to enrollees that, in cases where non-contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.
7. Information regarding out-of-area coverage and emergency coverage, including the process and procedures for obtaining emergency services, and the location where emergency care can be obtained, as well as other locations where contracting physicians and hospitals provide emergency services, and post-stabilization care included in the MA plan;
8. Prior authorization rules and other review requirements that must be met in order to ensure payment for the services; and
9. A general disclaimer that indicates that the directory is current as of a particular date and that a provider's listing in the directory does not guarantee that the provider is still in the network or accepting new members.

PCP and Specialty Directories: Medicare health plans may publish separate PCP and Specialty directories provided that both directories must be given to enrollees at the time of enrollment and at least annually thereafter. Organizations that use sub-networks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate sub-network) and describe any restrictions imposed on members that use these sub-networks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. Organizations must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

Medicare health plans may print a separate directory for each sub-network and disseminate this information to members in a particular sub-network. This practice is permissible, provided that the directory clearly states that a directory that lists providers for other networks is available and provides this information to members upon request.

Mailing the Provider Directory to Addresses with Multiple Members: With respect to the annual mailing of the directory, Medicare health plans have the option to either mail one directory to every member, or to mail one directory to every address where **up to four members** reside. (Keep in mind that individuals in, for example, apartment buildings, are only considered to be at the "same address" if the apartment number is the

same.) Please note that every member must still receive his or her own directory at the time of enrollment.

If you choose to mail the directory to every address where up to four members reside, you must keep the following in mind:

- If a member at that address subsequently requests that you mail another copy of the directory, you must mail them a directory.
- When mailing a directory to one address, you should include the name of at least one of those individuals in the mailing address (however, we prefer that you include the names of all individuals, to prevent any members mistakenly believing that you failed to mail them a directory).

Changes to Provider Network: *MA organizations must make a good faith effort to provide notice of termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified*

Provider Directory Change Pages: *MA organizations that has a web site or provides MA plan information through the Internet must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an internet web site. (Exception: Employer Group plans can direct members to their employer for information on the EOC and SB.) With respect to those members who choose to receive a hard copy directory as opposed to an electronic copy, Medicare health plans have the option to mail a complete directory to members, or to instead mail only change pages to members. (Note that CMS still requires that every member receive a complete directory at the time of enrollment.) In addition, if at any time a member requests a complete directory, the organization must comply with the request.*

If an organization chooses to send change pages to members, the following will also apply:

- In instances where significant changes to the provider network occur, the organization must send a special mailing of change pages immediately. In general, the organization can define “significant changes” when determining whether a special mailing is necessary. However, the CMS may also determine a mailing is needed and may direct the organization to conduct such a mailing.
- A new, complete provider directory must be mailed to all members at least every three years.

- Change pages may consist of the actual page being changed or a list of changes with referenced pages. Change pages must be dated.
- When sending out change pages, the organization must include a cover letter that explains that the member can receive a complete directory upon request. The organization should also include information on how to obtain provider network information on the Internet and/or by telephone. In addition, the first time the organization sends change pages the cover letter should explain that the organization will now be sending change pages to members, as opposed to a complete directory.

Please also refer to §40.1.C, Item #1, which contains more information regarding mailing of the Provider Directory.

40.3 - Specific Guidance About Drug Formularies

(Rev. 15, 09-27-02)

In providing a prescription drug benefit, a health plan/MA organization may rely on a formulary. A formulary is a list of prescription drugs, grouped by therapeutic drug class. There are three categories of formularies: open, preferred, and closed. Open formularies list all drugs and drug products that are covered and do not place restrictions on coverage of drugs within each therapeutic class (i.e. the physician can order any one in the class). Preferred formularies are similar to open formularies, but also use incentives and interventions to encourage use of certain preferred drugs. Closed formularies use limited lists of drugs; enrollees pay penalties (sometimes the entire cost) for drugs not on the formulary.

Many health plans/MA organizations make periodic changes to formularies or the items on preferred lists, often convening meetings of their pharmacy and therapeutics committees several times a year to add and remove items from the formulary or preferred list. When they enroll in a MA plan, beneficiaries may not be aware that changes to formularies or preferred lists are likely to occur during the contract year.

Every health plan/MA organization that covers outpatient prescription drug benefits (those not covered under the original Medicare fee-for-service program) must provide notice in its Evidence of Coverage (EOC) whether it uses a formulary or preferred list. If it uses formularies or preferred lists, the notice shall include:

- An explanation of what a formulary is;
- A statement that the formulary (or drugs on the preferred list) may change during the contract year;
- An estimate of how often the health plan/MA organization reviews the contents of the formulary and makes changes based upon that review;

- A description of any process by which a prescribing provider may obtain authorization for a non-formulary or non-preferred list drug to be furnished under the same terms and conditions as drugs on the formulary or preferred list; and
- A statement that members may use health plan/MA organization grievance and appeals process if they have complaints about the formulary or its administration.

In addition, health plans/MA organizations that use formularies or preferred lists must disclose whether specific drugs are on the health plan/MA organizations' formularies or preferred lists when enrollees or potential enrollees make telephone or other inquiries.

With respect to pre-enrollment marketing materials that describe plan benefits, health plans/MA organizations must disclose whether a formulary or preferred list is used and that the formulary or list may change during the contract year and provide a contact number that the beneficiary can call for more information. This policy will be effective beginning in contract year 2001 and will be incorporated into the Model EOC for 2001.

40.4 - Conducting Outreach to Dual Eligible Membership

(Rev. 15, 09-27-02)

A number of MA plan members are, due to financial status, eligible for State financial assistance through State Medicaid Programs. This assistance provides them an array of financial savings ranging from partial payment of Medicare Part B premiums to full payment of Medicare premiums and other plan cost sharing. Historically, some of those eligible do not apply for these State savings programs because:

1. The individuals equate Medicaid with Welfare and associate a social stigma to the terms;
2. They are not aware of the savings that are available;
3. They do not understand the eligibility requirements; or
4. They find the process sometimes complex and difficult to understand.

Some MA organizations choose to conduct outreach to their MA members to educate them and to assist them in applying for these savings programs. This may be especially true because CMS capitates MA organizations at a higher rate for some dual eligible members.¹² The CMS encourages but does not require MA organizations to assist their members with applying for State financial assistance because of the potential benefits to both the members and to the MA organizations.

This section instructs MA organizations in outreach program requirements and the process for submitting those programs and member materials (e.g. letters, call scripts,

etc.) to CMS for approval. It also provides CMS staff with operating procedures for reviewing and approving the outreach programs.

40.4.1 - General Guidance on Dual Eligibility

(Rev. 28, 08-01-03)

There are several categories of dual eligibility, each having specific income requirements and providing different levels of financial assistance to those who qualify at that level. The categories are outlined in the following chart:

Additional information is available at <http://www.cms.hhs.gov/medicaid/>. Income Requirements for Hawaii and Alaska specifically noted. Resource and Income Limits shown below may vary by state; contact the state for specific resource amounts. . *The below chart reflects FY 2003 information. Will be revised with up to date information.*

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
QMB only Qualified Medicare Beneficiary without other Medicaid	\$769 – individual \$1,030 – couple Alaska: \$955 –individual \$1,282 – couple Hawaii: \$881 – individual \$1,182 – couple	Medicare premiums, deductibles, and coinsurance. No Medicaid services.	Medicare	QMB rates for Medicare deductibles and coinsurance
QMB Plus Qualified Medicare Beneficiary with Full Medicaid	\$769 – individual \$1,030 – couple Alaska: \$944 – individual \$1,282 – couple Hawaii: \$881 – individual \$1,182 – couple	Medicare premiums, deductibles, and coinsurance. Medicaid services.	Medicare Medicaid	QMB rates for Medicare deductibles and coinsurance Medicaid rates for Medicaid services only.
SLMB only Specified	\$918 – individual	Medicare Part B premiums.	Medicare	No liability for Medicare deductibles

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
Low-Income Medicare Beneficiary without other Medicaid	\$1,232 – couple Alaska: \$1,141 – individual \$1,534 – couple Hawaii: \$1,053 – individual \$1,414 – couple	No Medicaid services.		and coinsurance.
SLMB Plus Specified Low-Income Medicare Beneficiary with Full Medicaid	\$918 – individual \$1,232 – couple Alaska: \$1,141 – individual \$1,534 – couple Hawaii: \$1,053 – individual \$1,414 – couple	Medicare Part B premiums. Medicaid services.	Medicare Medicaid	No liability for Medicare deductibles and coinsurance. Difference between Medicare payment and Medicaid rates for Medicaid services.
QI-1 Qualifying Individuals - 1	\$1,031 – individual \$1,384 – couple Alaska: \$1,282 – individual \$1,725 – couple Hawaii: \$1,183 – individual \$1,589 – couple	Medicare Part B premium.	Medicare	No liability for Medicare deductibles and coinsurance.
QDWI Qualified Disabled and Working Individuals	\$3,078 – individual \$4,125 – couple Alaska: \$3,822 – individual \$5,132 – couple	Medicare Part A premium.	Medicare	No liability for Medicare deductibles and coinsurance.

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
	Hawaii: \$3,528 – individual \$4,732 – couple			

40.4.2 - Guidelines for Outreach Program

(Rev. 35, 10-31-03)

In order to assure CMS that MA organizations' outreach programs effectively assist members while protecting them from undue pressures or privacy violations, MA organizations ¹³ must adhere to the following guidance.

The MA organizations MUST:

1. Provide outreach to all levels of dual eligibles, including those levels that do not provide MA organizations with additional capitation amounts from CMS. All outreach materials (e.g., member letters (see §40.4.5 for a model Direct Mail Letter), telephone scripts) must include eligibility information that includes QI-1 and QI-2 levels. [See footnote 12 for clarification.]
2. Clarify in outreach materials that the member may voluntarily offer information, including financial information, but that the member is not obligated to provide this information.
3. Clarify in outreach materials and discussions with members that the member's failure to provide information will in no way adversely affect the beneficiary's membership in his or her health plan.
4. Clarify in outreach materials, including member letters, that the Medicare Savings Programs are part of either the "State Medicaid program" or "state medical assistance programs".
5. State in materials and discussions with members that the MA organization will not share the information with any other entity not directly associated with determining eligibility or under contract to participate in the outreach process.
6. Clarify in outreach materials that the MA organization is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination.

7. Provide guidance to a member on how to proceed with the application process even if the MA organization's screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs.
8. Provide adequate training to staff conducting the outreach. If the MA organization subcontracts this effort to another entity, it must ensure that the subcontractor's staff is adequately trained to provide outreach.
9. Include alternate sources of information in outreach materials. Member letters and/or brochures that contain outreach information telephone numbers must also include the telephone number for the State Health Insurance Assistance Program (SHIP) and the appropriate State Agency. Outreach materials may also include the telephone number for the Medicare Service Center (1-800-MEDICARE).
10. Include privacy guidelines in outreach materials, telephone scripts, and internal processes and/or contracts with entities performing outreach for the MA organization. Contractual privacy guidelines must clearly state that all financial information collected from members of the MA organization will not be used for any other purpose by the entity collecting the data. Privacy guidelines must also state that entities involved in the outreach will not share member information with anyone not involved in the outreach process.
11. Ensure that contracts with entities taking part in some aspect of outreach activities meet MA Administrative Contracting requirements listed in the Medicare Managed Care Manual, Chapter 11, §100.5.
12. Work closely with CMS' regional office staff during the outreach submission and review process so that CMS can work cooperatively with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach process initiation.

The Medicare Advantage Organization MAY:

1. Conduct outreach for only a portion of its plan membership. Selection of the focus population may be based upon demographic data and/or may focus on a specific geographic area. However, the organizations must provide outreach to all individuals within those pre-identified population segments. Additionally, if the organization receives an inquiry from a Plan member not previously identified in the targeted group, it must provide assistance to that member as if he or she had been included on the outreach list.
2. Provide hands-on assistance to the member in completing all necessary applications for financial assistance including submitting the paperwork to the appropriate State office. This assistance can be in the member's home only if the member requests such a visit.

3. Use the “Authorization to Represent” limited to the specific purposes of completing and submitting paperwork on behalf of the member, discussing the member’s case with case workers, representing the member in cases of appeal, and gather information from and on behalf of the Plan member. The “Authorization to Represent” form must specify that the authorization is limited to securing benefits under “the Medicare savings program” or “the Medicaid Program” and cannot extend to other programs unless agreed upon and noted by the member. “Authorization to Represent” shall not give the outreach specialist the authority to sign any documents on behalf of the member nor make any enrollment decisions for the member.
4. Follow-up with members who do not respond to the initial member letter. This follow-up may be in the form of a second and/or third letter or telephone calls. If the member does not respond to the third effort, the MA organization refrain from contacting the member for at least six months following the last outreach attempt.
5. Provide assistance to members reapplying for financial benefits if and when required to do so by the state agency.
6. Subcontract all outreach efforts to another entity or entities. In such cases, while the MA organization retains all responsibility for meeting CMS’ requirements, it must still submit all documentation to CMS for approval including contracts held by the subcontractor with all entities related to the program. The MA organization must also coordinate changes and revisions between the subcontractor and CMS.

The Medicare Advantage Organization Shall NOT:

1. Conduct door-to-door solicitation or outreach prior to receiving an invitation from the member to provide assistance in his or her home.
2. Share any member information, financial or otherwise, with any entity not directly involved in the outreach process.
3. Store or use member financial information for any purpose other than the initial screening eligibility, the submission and follow-up of an application for benefits, for recertification purposes, and as required by law.
4. Contact any member who has refused outreach assistance or who has not responded to the telephone call or follow-up letter until at least six months following the last outreach attempt.
5. Infer in any written materials or other contact with the member that the organization has the authority to determine the member’s eligibility for state assistance programs.

40.4.3 - Submission Requirements

(Rev. 28, 08-01-03)

To facilitate CMS' review of outreach programs, an MA organization must submit one copy of the materials listed below to its Central Office Plan Manager, one copy to the Regional Office Plan Manager, one electronic copy to the Dual Eligibility Outreach Product Consistency Team (PCT), ¹⁵ and the Regional Office Plan Manager.

1. Detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow chart showing the result of each action.)
2. Timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area (e.g., county) included in the activities. This is to allow CMS to more accurately coordinate outreach activities with its partners (e.g., SHIP, State Agencies).
3. Executed contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.
4. Supporting documentation from the appropriate State Agency providing specific state income requirements for each savings program level, and names and contacts within the appropriate State Agency/agencies.
5. Outreach letters and other materials (e.g., brochures, Authorization to Represent form) going to plan members.
6. Internal training programs the organization is using to educate staff involved in outreach.
7. Telephone scripts or other outreach assistance scripts that will guide representatives in answering members' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the member is not required to provide any information to the representative and that the information provided will in no way affect the beneficiary's membership in the plan.
8. Internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.

In some instances, an MA organization may chose to submit an outreach proposal that CMS has already approved for use by another MA organization. This is common when an MA organization is part of a national organization with multiple contracts, each of which is conducting its own outreach. This is also common when a subcontracting entity designs and conducts the outreach. These subcontractors often seek to contract with

multiple MA organizations and conduct the same outreach programs for each of their clients.

If an MA organization submits an outreach proposal that (a) CMS previously approved on or after April 1, 2002; (b) That CMS approved within the twelve months prior to the submission; and (c) That does not contain substantive changes ¹⁴ to qualify it as an “initial” proposal, the MA organization must submit the items listed above (1 - 8) in addition to the following:

An attestation from either the MA organization or its contracted outreach vendor stating (a) That the proposal has been approved by CMS, (b) The date of that approval, and (c) That the new submission does not contain substantive changes to the approved program.

Section 40.4.4 contains a description of CMS’ review process and time frames for both initial and previously approved proposals.

40.4.4 - CMS Review/Approval Process

(Rev. 28, 08-01-03)

NOTE: The CMS review process for new outreach proposals differs from the review process for previously approved outreach proposals. The processes for both submissions are stated below.

Reviewing New Outreach Programs

1. The MA organization is responsible for submitting the outreach proposal to CMS and working with CMS through the review and approval process even if a subcontractor developed the proposal. The CMS will hold the MA organization fully responsible for all the provisions of the outreach program and for assuring the members of their rights and protections outlined in the MA program regulations.
2. In that CMS considers outreach materials to be a form of marketing, CMS will review outreach proposals according to current time frames for reviewing marketing material. The agency will conduct its initial review and provide comments to the MA organization within 45 days of receipt of a new (not previously approved) proposal.
3. As noted in §40.4.3, MA organizations must submit one complete copy of the materials listed in §40.4.3 to the CMS Central Office Plan Manager, a second copy of the same materials to the CMS Regional Office Plan Manager, and an electronic copy of the materials to the Dual Eligibility Outreach (PCT)¹⁵. If a proposal incorporates states in regions other than those represented above, the PCT ensures that the appropriate Regional Office Plan Manager receives a copy

of the proposal for comment from the National Account Representative (NAR) for the state(s).

The Dual Eligibility PCT will review all the enclosed documentation in conjunction with the Plan Managers and will provide comments to the Central and Regional Office Plan Managers. The Regional Office Plan Manager will relay CMS comments back to the MA organization will gather revisions (when necessary) and will finish the review and approval process based upon the MA organization's revisions.

4. The Regional Office Plan Manager will share outreach materials with the appropriate NARS and state representatives. The NARS and state representatives should, at a minimum, share the member letters with the State agency as a way to verify the accuracy of the information contained in the proposal and to receive input from state partners.
5. Upon final approval of the proposal and outreach materials, the Regional Office Plan Manager will send an approval letter to the MA organization.
6. The Regional Office will then contact its partners (SHIPs, State Medicaid Offices, etc.) to notify them of the outreach effort and possible increase in beneficiary inquiries. The Regional office will share copies of outreach letters with the State Agencies to prepare them for incoming questions.

Reviewing Previously Approved Outreach Programs

If an MA organization submits an outreach proposal that CMS has already approved and that does not contain substantive changes (outlined in §40.4.3), then the CMS Regional Plan Manager, in conjunction with the appropriate NARs, will only review the targeted membership information (audience number and outreach dates), the contract(s) between the MA organization and its outreach subcontractor(s), the updates to benefit levels and income and resource criteria, and the attestation. The CMS will respond to the MA organization within the 10-day time frame CMS has established for reviewing standardized marketing materials. The CMS' Regional office will file the outreach proposal for future reference. The CMS recognizes that the MA organization will have to make simple periodic changes to their outreach programs in order to update minimum income levels, etc. As stated previously (in footnote 14), CMS does not consider these updates to be "substantive changes" in that they do not prompt a full review of an outreach proposal. However, the MA organization is still responsible for submitting such changes to the appropriate CMS regional office for marketing review to ensure accuracy of such changes.

If the MA organization wishes to make substantive changes to the outreach process, it must submit those changes to the appropriate CMS Central Office and Regional Office Plan Managers for review through the PCT according to the review process above.

40.4.5 - Model Direct Mail Letter

(Rev. 28, 08-01-03)

(Data valid for 2003)

August 25, 2003

Mr. Frank Smith
123 Maple Lane
Anywhere, USA 12345

Dear Mr. Smith,

Did you know you may be able to save up to \$704.40 a year on Medicare expenses?

States have programs that pay some or all of Medicare premiums, may also pay Medicare deductibles and coinsurance, and Medicare health plan premiums. These programs are administered as part of the State Medical Assistance Program.

If you answer “yes” to ALL three of these questions, then you may qualify for Savings for Medicare Beneficiaries.

- Do you have Medicare Part A, also known as hospital insurance? If you are eligible for Medicare Part A, but do not have it because you cannot afford it, you may still qualify because there is a program that will pay the Medicare Part A premium.
- Are you an individual with a monthly income of less than \$1,031 or a couple with a monthly income of less than \$1,384?
- Are you an individual with savings of \$4,000 or less or a couple with savings of \$6,000 or less? Savings include things like money in a checking account or savings account, stocks, or bonds. When you are figuring out your savings, do not include your home, a car, burial plots, up to \$1,500 for burial expenses, furniture, or \$1,500 worth of life insurance.

If you have a disability and lost your Medicare because you returned to work and are eligible to purchase Medicare Part A benefits, you should also apply. To qualify, you must be an individual with a monthly income of less than \$3,078 and resources of \$4,000* or less. Or, you must be a couple with a monthly income of less than \$4,125 and resources of \$6,000* or less.

* Individual states may have more generous requirements.

Enclosed is a brochure that gives you more information about the programs that can help you save on your medical expenses, information on who qualifies, and how to apply for the programs.

I hope you will call me between 9 a.m. and 5 p.m. Monday through Friday at (your phone number here) for more information or for help joining one of these programs. All information that you share will only be used to determine if you may be able to get help with your medical expenses. I will not share the information with anyone else. I encourage you to call to see if you can receive help with your medical expenses, but the choice is yours. You are not required to call. If you like, you can also receive information about the programs by calling a representative of the State Health Insurance Assistance Program at XXX or a State representative at XXXX. Deaf or hearing-impaired people who use a TTY/TDD can call Medicare's national help line at 1-800-486-2048. When you call, ask about programs that can help with Medicare expenses.

40.5 - Specific Guidance for the Standardized Summary of Benefits (SB)

(Rev. 20, 04-04-03)

The standardized Summary of Benefits (SB) is a stand-alone marketing document that is generated from the Plan Benefit Package. It is the primary pre-enrollment document used by MA organizations to inform potential Medicare beneficiaries of plan benefit packages offered by MA organizations.

40.5.1 – Summary of Benefits for Medicare Advantage Organizations

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

Medicare Advantage organizations and Demonstration projects are required to use a standardized SB.

A. General Instructions

1. MA organizations must adhere to the language and format of the standardized SB and are only permitted to make changes if approved by CMS. Changes in the language and format of the SB template will result in the disapproval or delayed approval of the SB. *Guidelines for the requests to change the Hard copy Summary of Benefits can be found in 40.5.3.*
2. The title “Summary of Benefits” must appear on the cover page of the document.
3. All three sections of the SB must be provided together as one document and may not be bound separately or placed in a folder in separate sections. MA organizations may also describe several plans in the same SB package by displaying them in separate columns in the comparison matrix section of the SB.

4. Front and back cover pages are acceptable.
5. Printing font size of 12-point or larger must be used for the SB (including footnotes). **NOTE:** Since sections 1 and 2 will not be generated from the PBP in 12-point font, the MA organization should change the font to ensure that the font size is 12 point. MA organizations may enlarge the font size and also use bold or capitalized text to aid in readability, provided that these changes do not steer beneficiaries to, or away from any benefit items or interfere with the legibility of the document.
6. Colors and shading techniques, while permitted, must not direct a beneficiary to or away from any benefit items and must not interfere with the legibility of the document. There is no requirement regarding the type of paper used.
7. It is acceptable to print the SB in either portrait or landscape page format.
8. It is acceptable for MA organizations with multiple plans and PBPs (separate Bids) to include more than one plan in the benefit comparison matrix (section 2). However, since the PBP will only print section 1 and 2 reports for one plan, the MA organizations will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format.
9. It is acceptable for MA organizations to display more than one plan together in the same columns of the benefit comparison matrix, provided all of the benefits are the same and only the service areas are different. Plans may identify the service areas at the top of the plan column of section 2. **NOTE:** If anything beyond the service area is different, the plans must be displayed separately.
10. If the SB includes only one of several plans offered, the availability of other plans must be noted in the Annual Notice of Change (ANOC). If the MA organization lists more than one plan offering, it is required to identify the specific plan in which the member is currently enrolled on the cover letter transmitting the SB.
11. If an MA organization wants to include mandatory supplemental benefits beyond those benefits found in the benefit comparison matrix, the MA organization must place the information in section 3 of the SB. The MA organization must include a brief description of the benefits and any copay requirements.
12. If an MA organization includes additional information about covered benefits in section 3, the MA organization may include a page reference to this information in the appropriate box in the benefit comparison matrix using the following sentence: "See page___ for additional information about (Enter the benefit category exactly as it appears in the left column)."

13. MA organizations may include additional information about covered benefits in a separate flyer or other material and mail this with the standardized SB and the Annual Notice of Change Letter.
14. Enrollees whose source of enrollment is through an employer-sponsored group are not currently included in the mandated use of the standardized SB for either annual notification or initial marketing purposes.
15. *The SB header containing such information as the company name, customer service telephone number etc., only displays on the first page of the SB section 2. It is acceptable for MA organizations to display SB header on each page or on each section of the SB.*
16. *SB section 3 is used by the MA organization to describe special features of the MA organization beyond information contained in sections 1 and 2 of the SB. Section 3 may contain non-standardized language, graphics, pictures, maps, etc. This section of the SB is not a mandatory but optional. Therefore, if an organization chooses to submit the SB for CMS review without the section 3, it will be treated as model without modification which is within the 10-day time frame.*

B. Section 1 - Beneficiary Information Section

1. This section is incorporated into your SB exactly as it is generated by the PBP.
NOTE: MA organizations have the option of indicating at the top of this section a geographic name, for example, “Southern Florida.” If used, the geographic name must match the geographic label indicated in the Health Plan Management System (HPMS).
2. Section 1, as generated by the PBP, will include the applicable H number and plan number at the top of the document. MA organizations must delete this information.
3. The fourth paragraph (How can I compare my options?) contains a sentence “We also offer additional benefits, which may change from year to year.” If this is not applicable to your plan, you must remove this sentence.
4. The second question and answer in section 1 includes the plan’s service area; the PBP will generate a list of counties, with an * indicating those counties that are partial counties. The MA organization may list the zip codes of these counties in this section or provide a cross-reference in section 3 and list the zip codes here. The MA organization must also explain in section 1 that the * indicates a partial county.
5. The second question and answer in section 1 lists the plan’s service area, but does not indicate that the information listed represents counties. Therefore, the MA

organization must amend the SB so that the answer reads, “The service area for this plan includes the following counties: [list of counties automatically generated by the PBP].”

6. The last sentence in section 1 on page 2 states, “If you have special needs, this document may be available in other formats.” MA organizations contracting with CMS are obligated to follow the regulatory requirements of the American with Disabilities Act and the Civil Rights Act of 1964. Compliance with these requirements satisfies the intent of the above referenced SB sentence. No additional requirements are imposed by the above referenced SB sentence.

C. Section 2 - Benefit Comparison Matrix

The SB benefit comparison matrix will be generated by the PBP in chart format with the required language. Therefore, the information included in the PBP must first be correct in order for the SB comparison matrix to be correct. MA organizations should review the comparison matrix to ensure that all of the information presented is correct. Information presented in the benefit comparison matrix must match the information presented in the PBP, with the exception of the permitted and/or necessary changes discussed below. If any changes are required, the MA organization must make these changes in the PBP prior to the deadline date for submission of the BIDSP, generate a revised SB benefit comparison matrix, and include this matrix in its SB.

If the MA organization follows Option 1 of the streamlined marketing review process (as addressed in §20.3), then the CMS reviewer will have the benefit comparison matrix that is generated by the PBP and will compare this with the matrix provided as part of the plan’s SB. Any discrepancies between the matrix generated by CMS and that provided by the plan (with the exception of those permitted below) will result in disapproval of the SB. If the MA organization follows Option 2 of the streamlined marketing review process, this comparison will not occur during the review since CMS is not reviewing Section 2 of the SB.

D. Section 3 - Plan Specific Features

This section is limited to a maximum of six pages of promotional text and graphics and is not standardized with regard to format or content. The 6-page limit means that the information is limited to six single-sided pages or 3 double-sided pages. However, there is one exception to this limit:

- When an MA organization is translating the SB to a foreign language, it may add pages as necessary to ensure the translation conveys the same information as the English language version.

Section 3 is used by the MA organization to describe special features of the MA organization beyond information contained in sections 1 and 2 of the SB. Section 3 may contain non-standardized language, graphics, pictures, maps, etc.

MA organizations may use this section to further describe mandatory and optional supplemental benefits that appear in the benefit comparison matrix. If an MA organization chooses to do this, they may reference the information in the relevant section of the benefit comparison matrix using the following sentence: “See page___ for additional information about (Enter the benefit category exactly as it appears in the left column.)” Section 3 is not intended to include a description of every plan benefit not included in Section 2 that has cost sharing associated with it.

If an organization chooses to submit the SB for CMS review without the section 3, it will be treated as model without modification which is within the 10-day time frame.

E. Permitted Changes To SB Language and Format

MA organizations are only permitted to make changes to the benefit matrix or Hard Copy Summary of Benefits on a limited basis. **Any changes** must be approved by CMS. Please refer to §40.5.3 for further detail.

F. Footnotes

The comparison matrix generated by the PBP will contain the required footnotes in the benefit column for Original Medicare (OM). Therefore, the MA organization must include the following footnotes provided below if they apply to the benefit. Please note that the footnote number must appear in the text of the column and the footnote must appear at the bottom of each page.

NOTE: For review purposes, the MA organization can list all of the footnotes at the end of section 2, but the final proof copy must include the footnotes at the appropriate points in the text. If the MA organization chooses this option, the MA organization must notify the CMS Regional Office conducting the review and must indicate in the SB where the footnotes will actually appear in the final printed version.

1. 2005, you pay a total of one \$110 deductible.

This footnote must be referenced after every statement in the Original Medicare column that describes the required Medicare coinsurance, e.g., “You pay 20% of Medicare approved amounts.” The only exception where footnote (1) does not need to be referenced is mammograms, pap smears/pelvic exams and prostate cancer screening exams. If the footnote is applicable to the plan it must also be referenced in the Plan column. This footnote must also appear at the bottom of each page.

Note: The Medicare Part B deductible may change each year.

2. If a doctor or supplier chooses not to accept assignment, their costs are often higher, which means you pay more.

This footnote must be referenced after every statement in the OM column that describes the following benefits and after footnote (1), where applicable. The text of this footnote must appear at the bottom of each page.

3. A benefit period begins the day you go to the hospital or skilled nursing facility. The benefit period ends when you have not received hospital or skilled nursing care for 60 days in a row. If you go into the hospital after one benefit period has ended, a new benefit period begins. You must pay the inpatient hospital deductible for each benefit period. There is no limit to the number of benefit periods you can have.

This footnote must be referenced after the words “benefit period” in the OM column describing Inpatient Hospital Care and Skilled Nursing Facility and the text of this footnote must appear at the bottom of the page on which these benefits are described. Additionally, if the footnote is applicable to the plan it must also be referenced in the Plan column.

4. Lifetime reserve days can only be used once. This footnote must be referenced after the statement, “Days 91-150: \$ (The Medicare amount may change each year) each lifetime reserve days” in the OM column describing Inpatient Hospital Care. Additionally, if the footnote is applicable to the plan it must also be referenced in the Plan column. The text of this footnote must appear at the bottom of the page on which these benefits are described.

40.5.2 -Summary of Benefits for Cost Plans

(Rev. 20, 04-04-03)

Cost plans are not required to use the standardized Summary of Benefits, however they are required to provide members with an SB. If a cost plan intends to have the plan appear in Medicare Health Plan Compare and Medicare Personal Plan Finder, it will need to complete the Plan Benefit Package (PBP) to create a standardized SB. Cost plans that create a standardized SB should follow all instructions below.

Cost plans should follow all instructions outlined in §40.5.1 for MA organizations. In addition, the following instructions are specific to cost plans.

A. General Instructions

1. The benefit description column and Original Medicare column must remain unchanged.

2. All sentences in the plan column of the matrix must be completed with applicable copays or coinsurance amounts.
3. Additional instructions provided in italicized text and in parentheses should be removed from the Summary of Benefits prior to submitting the document to CMS for review.
4. Unless otherwise indicated, cost plans should choose all of the applicable sentences in each category to describe their benefits.

B. Section 1- Beneficiary Information Section

For cost plans that are “closed” to new enrollment, the pre-enrollment language in section 1 will not apply. Therefore, these cost plans should include the following disclaimer in their ANOC. Any additional information regarding the contractor’s “closed status” should also be included in the cover letter.

The CMS requires the Summary of Benefits (SB) to be used in both pre-enrollment and annual notice of change (ANOC) functions. Plan member receiving the SB should disregard all pre-enrollment language.

C. Section 2 - Benefit Comparison Matrix

Cost plans may include the following footnote on each page of the benefit comparison matrix. The text of the footnote should appear at the bottom of every page.

If you go to a provider outside of [insert name of plan] who accepts Medicare patients, your coverage would be the same as Original Medicare. Original Medicare deductibles and coinsurance apply.

40.5.3 - Requests to Change Hard Copy Summary of Benefits

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The CMS will allow an organization to make changes to hard copy SBs on a very limited basis. The organization must receive approval from the CMS Central Office prior to making any changes. Any approved changes will NOT result in changes in Medicare Personal Plan Finder, nor will they result in changes to the Plan Benefit Package. However, requests may be considered for future changes to the Plan Benefit Package.

What types of Changes will be Permitted?

The only changes that will be permitted are those that would correct inaccurate or misleading information presented to beneficiaries in the hard copy SB. For example, if a plan does not have a network, a change **may** be permitted to remove a sentence referring to the requirement that members see doctors within the plan’s network.

What types of Changes will NOT be Permitted?

Requests for changes in which the existing sentences are accurate will not be permitted. MCOs will **NOT** be permitted to add additional sentences in Section 2 of the Summary of Benefits in order to further explain their benefits. The CMS will not allow changes in wording, based on individual preferences.

How to request a change?

To request a change to the hard copy SB, e-mail your request to SummaryofBenefits@cms.hhs.gov. The subject line in the request must read: “Hard Copy SB Change Request.” In the request, provide:

1. The H number and Plan ID—each H number and Plan ID should be in a separate e-mail;
2. The Regional Office and Contact who review the MCO marketing material;
3. The existing standardized Summary of Benefits language;
4. An explanation of why the existing standardized language is inaccurate; and
5. A modified sentence.

How will CMS review the requests?

A cross-functional workgroup reviews each request. The workgroup will determine if the current standardized wording is inaccurate or misleading. If the workgroup denies the request, CMS will notify the MCO and the MCO must adhere to the standardized language. If the workgroup permits a change, CMS will notify the MCO with the approved language. Note that the approved language will be decided by CMS and will be considered “standardized.” The CMS will also notify the Regional Office of the approved language. If the request is based on a preferred wording, the request will not be approved.

40.6 – Specific Guidance on the Evidence of Coverage

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

All organizations are required to give an EOC to all members annually. They must also send new members an EOC no later than when they notify the member of acceptance (confirmation) of enrollment (the time frame requirements for sending notice of acceptance of enrollment are contained in Chapter 2, Section 40.4.2). These requirements apply to all plan members, including employer group

members. CMS provides a model EOC for HMOs, PPOs, and Medicare cost plans under separate cover.

In addition to the guidance provided in §§40.1 and 40.3, the following information must be contained in the EOC:

Lock-In Requirements/Selecting a Primary Care Physician - How to Access Care in the plan

Medicare health plans must describe rules for receipt of primary care, specialty care, hospital care, and other medical services in their EOC. The EOC must:

- Disclose specific rules for referrals for follow-up specialty care.
- HMOs: Explain that when a beneficiary enrolls in a plan, he/she agrees to use the network of physicians, hospitals, and providers that are affiliated with the plan for all health care services, except emergencies, urgently needed care, or out-of-area renal dialysis services.
- Explain that use of non-plan or non-preferred providers is allowed, but may cost more to the beneficiary (this requirements applies to PPOs and POS plans and, if appropriate, Visitors Programs for any plan type).
- Explain the impact of using the Medicare card for out-of-plan utilization that is not an emergency or urgent care.
- Explain that a plan member selects a primary care physician (PCP) to coordinate all of the member's care. A PCP is usually a family practitioner, general practitioner, or internist. The PCP knows the plan's network and can guide the member to plan specialists when needed. The member always has the option to change to a different PCP. Changes in PCP will be effective according to the plan guidelines that, in some instances, could be the first or the 15th day of the following month as opposed to immediately. (This requirement does not apply to PPOs or PFFS plans that do not use PCPs.)
- For HMOs, explain that neither the MA organization nor Medicare will pay for medical services that the member receives outside of the network unless it was authorized, or it is an emergency, urgently needed care, or out-of-area dialysis service. The member may be responsible for paying the bill.
- For PPOs, explain that with the exception of emergency or urgent care, it may cost more to get care from non-plan or non-preferred providers.
- Explain prior authorization rules for any in or out-of-network services and describe other review requirements that must be met in order to ensure payment for the services

- For Medicare cost plans, enrollees must be informed that after enrollment is effective, in order for them to receive the full coverage offered, services other than emergency and urgently needed services must be obtained through the HMO or CMP. In the case of cost enrollees, however, they may receive services that are not provided or arranged by their HMO or CMP, but they would be responsible for payment of all Medicare deductibles and coinsurance as well as any additional charges as prescribed by the Medicare program. They also would be liable for any charges not covered by the Medicare program.

Emergency Care

EOCs must describe rules for emergency care and post-stabilization care. In particular, they must:

- Explain that members are not required to go to health plan-affiliated hospitals and practitioners when they experience an emergency.
- MA organizations: Define the term “Emergency medical condition (this definition can be found in [Chapter 4](#)).
- Define the term “Emergency services” (MA organizations can find this definition in [Chapter 4](#); Medicare cost plans can refer to [42 CFR 417.401](#).)
- Describe rules and coverage for post-stabilization care. MA organizations can refer to Chapter 4 and [42 CFR 422.113\(b\)\(3\), \(c\)\(2\)\(i\) through \(iii\)](#) for more information on responsibility for emergency care and stabilization and post-stabilization requirements.
- Describe precisely where emergency coverage will be available under the organization (e.g., the United States and its Territories, worldwide, etc.).

Urgent Care

EOCs must describe rules for urgent care. In particular, they must:

- Define “urgently needed services” (for MA organizations, this definition can be found in [Chapter 4](#), for Medicare cost plans, it is in [42 CFR 417.401](#)).
 - Explain that urgently needed care provided by non-plan providers is covered when a member is in the service area or MA continuation area under the unusual circumstance that the organization’s provider network is temporarily unavailable or inaccessible. Normally, if a member needs urgent care and is in the organization’s service area or MA continuation area, the member is expected to obtain care from the organization’s providers.

Appeal Rights

EOCs must describe the appeals process and rights to appeals. In particular, they must explain that members have a right to appeal any decision the organization makes regarding, but not limited to, a denial, termination, payment, or reduction of services. This includes denial of payment for a service after the service has been rendered (post-service) or denial of service prior to the service being rendered (pre-service). For more information on appeals, MA organizations can refer to Chapter 13.

Optional supplemental benefits cannot be appealed for Medicare cost plans. Therefore, Medicare cost plans must explain that complaints about Optional supplemental benefits are handled through the grievance process.

Benefits, Plan Premium and Billing Information

EOCs must describe benefit and plan premium information. In particular, they must:

- Include the statement: “You must continue to pay your Medicare Part B premium” with premium information, even if the plan premium is \$0.
- When specifying benefits, specify annual limits (e.g., \$1,000 annual maximum for prescription drugs), annual benefit payout (e.g., \$700 for eyeglasses every 2 years) and applicable co-payments (e.g., \$5 co-payment for a doctor visit).
- Clearly state major exclusions and limitations. For example, restriction of pharmacy benefits to a specific formulary or a restricted set of pharmacies must be explained.
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary’s access to drugs or services.
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits, and whether any unused portion of that benefit can be carried over from one calendar quarter to the next.
- Make the statement that the MA organization’s contract with CMS is renewed annually, and that the availability of coverage beyond the end of the current contract year is not guaranteed.
- Provide instructions to enrollees that, in cases where non-contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.

For more information on benefits, premiums and cost sharing, refer to Chapters 4 and 8.

50 - Guidelines for Promotional Activities

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

This section reviews the use of promotional activities relating to the enrollment and retention of members. Section 50.1 of this section provides general guidance about promotional activities, while §50.2 provides specific guidance for provider promotional activities. Section §50.3 describes CMS' policy with respect to the use of independent insurance agents for marketing purposes. Section 50.4 answers some frequently asked questions regarding all aspects of promotional activities.

50.1 - General Guidance About Promotional Activities

(Rev. 9, 04-01-02)

Promotional activities (including provider promotional activities) must conform to the requirements of §§1128A(a)(5) and 1128B(b) of the Act. Section 1128A(a)(5) of the Act provides for a civil monetary penalty against a person or entity that offers or transfers remuneration to a Medicare or Medicaid eligible individual that the person or entity knows or should know is likely to influence such eligible individual to receive or order services from a particular provider. Section 1128B(b) of the Act, the Medicare and Medicaid anti-kickback statute, prohibits the offering or giving of remuneration to induce the referral of a Medicare or Medicaid beneficiary, or to induce a person to purchase, or arrange for, or recommend the purchase or ordering of an item or service paid in whole or in part by the Medicare or Medicaid programs. Additional prohibitions on the offering of monetary rebates or inducements of any sort to enrollees are contained in §1854(d) of the Act.

50.1.1 - Nominal Gifts

(Rev. 5, 01-02-02)

Many health plans/MA organizations offer gifts to potential enrollees if they attend a marketing presentation. This is permitted as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the health plan/MA organization. Nominal value is defined as an item worth \$15 or less, based upon the retail purchase price of the item. Local Medicare fee-for-service fiscal intermediary and/or carrier charge listings can be used to determine the value of medical services, examinations, laboratory tests, etc., associated with nominal value determinations in marketing scenarios. Cash gifts are prohibited including charitable contributions made on behalf of people attending a marketing presentation, and including gift certificates that can be readily converted to cash, regardless of dollar amount. The dollar amount associated with the definition will be periodically reassessed by CMS. An organization may offer a prize of over \$15 to the general public (for example, a \$1,000 sweepstakes on its corporate Web site) as long as the prize is offered to the general public and not just to Medicare beneficiaries. When the whole company is offering a prize to individuals well beyond only Medicare individuals,

and that prize does not relate to a specific inducement to enroll in company products, the company should not exclude anyone with Medicare from being able to win the prize.

50.1.2 - Referral Programs

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The following general guidelines apply to referral programs under which Medicare health plans solicit leads from members of new enrollees. These include gifts that would be used to thank members for devoting time to encouraging enrollment. Gifts for referrals must be available to all members and cannot be conditioned on actual enrollment.

- Medicare health plans may not use cash promotions as part of a referral program.
- Medicare health plans may offer thank you gifts of less than \$15 nominal value (e.g., thank you note, calendar, pen, key chain) when an enrollee responds to a plan solicitation for referrals. These thank you gifts are limited to one gift per member, per year.
- A letter sent from the Medicare health plan to members soliciting leads cannot announce that a gift will be offered for a referral.
- An organization can ask for referrals from active members, including names and addresses, but cannot request phone numbers. Medicare health plans can then use this information for soliciting by mail.

50.1.3 - Health Fairs and Health Promotional Events

(Rev. 9, 04-01-02)

Many health plans/MA organizations are interested in offering health fairs or social events that promote health awareness and a sense of belonging among seniors. Health plans/MA organizations may participate in such events as either the sole sponsor of the event or as a member of a multiple-sponsor event. Application of the following CMS policies to the condition of sponsorship is indicated by **(Sole-Sponsor)** for sole sponsor events, **(Multiple-Sponsor)** for multiple-sponsor events, and **(Both)** where the policy applies to both single and multiple sponsor events. If an audience is comprised of the general public as well as Medicare beneficiaries, the following policies apply to the entire audience:

- Such events should be social and should not include a sales presentation. **(Both)**
Response by a health plan/MA organization representative to questions will not be considered a sales presentation if no enrollment form is accepted at the event. **(Both)**

- Advertisements for the event can be distributed to both members and non-members. (Both)
- The value of any give-away or free items (e.g., food, entertainment, and speaker) cannot exceed \$15 per attending person. For planning purposes, event budgets can be based on projected attendance. The cost of overhead for the event (e.g., room rental) is not included in the \$15 limit. (Both)
- Pre-enrollment advertising materials (including enrollment forms) can be made available as long as enrollments are not accepted at the event. (Both)
- If offered, door prizes/raffles cannot exceed the \$15 limit. (Sole-Sponsor)
However, door prizes/raffles can exceed the \$15 limit if a health plan/MA organization contributes to a pool of cash for prizes or contributes to a pool of prizes such that the prize(s) is not individually identified with the health plan/MA organization, but is identified with a list of contributors. A jointly-sponsored event may consist of the health plan/MA organization and one or more sponsor participants who are not contracting providers with the health plan/MA organization. A health plan/MA organization may also contribute cash toward prize money to a foundation or another entity sponsoring the event. For example: A radio station, along with many sponsors, puts together a senior fair. Anyone who attends may register for the door prize: a get-away weekend. The health plan/MA organization may participate in the fair, contribute to the door prize, and permit attendees to register for the prize at its booth (as well as other sponsor booths). However, the health plan/MA organization cannot claim to be the sole donor of the prize. It must be clear that the prize is attached to the seniors fair. No sales presentation may be made at the event. (Multiple-Sponsor)

50.1.3.1 - Employer Group Health Fairs

(Rev. 9, 04-01-02)

Enrollment restrictions (i.e., no sales presentations can be made or enrollment applications accepted at the meeting) do not apply to health fairs or other promotional events sponsored by an employer group or labor organization so long as the following requirements are met:

1. The meeting must be held solely for retirees and any active employees (and their spouses/interested decision makers) from the employer/labor organization. No “general public” persons may be solicited or invited to attend the meeting; and
2. The meeting may not be announced via “public media” vehicles. Potential employer group/labor organization retirees must be notified of the meeting by individual notification or by company/labor organization sponsored media such as a newsletter or similar targeted mailing/vehicle.

50.1.3.2 - CMS-Sponsored Health Information Fairs

(Rev. 9, 04-01-02)

The Centers for Medicare & Medicaid Services is required to conduct a nationally coordinated education and information campaign to inform Medicare Advantage eligible individuals about Medicare Advantage plans and the election process provided under the law for enrolling in Medicare Advantage plans. One of the coordinated education and information campaign activities is CMS sponsorship of Medicare Advantage Health Information Fairs.¹⁶ While most CMS-sponsored MA Health Fairs will be conducted immediately before and during the month of November each year (the Annual Election Period), occasionally CMS will sponsor Health Fairs as early as September and other times of the year. The following rules and procedures apply to CMS-sponsored Health Fairs, whenever they occur.

CMS will invite the MA organizations to participate in the planning of local Health Fairs. MA organization participation is optional, but it is important to get current contractors to the planning table. It is imperative that all CMS regions are consistent in applying participation guidelines at these **CMS-Sponsored** Health Fairs. Below are the guidelines. The CMS retains the right to modify these guidelines if CMS encounters a new situation that must be addressed.

50.1.3.3 - Allowable Actions for Medicare Advantage Organizations

(Rev. 28, 08-01-03)

Medicare Advantage Organizations may do the following:

- Assist in the planning of local Health Fairs;
- Distribute health plan brochures and application forms, while at the Health Fair.¹⁷ They may also include in their handouts a reply card which may be given to interested beneficiaries for return to the organization via mail;
- Have a booth at the Health Fair;
- Distribute items with a total retail value of no more than \$15. These items **MUST** be offered to everyone, (e.g., organizations can not give gifts to only those individuals who show interest;
- Have any personnel present (i.e., marketing personnel, customer service personnel) as long as they adhere to these guidelines;
- Contribute funding for any Health Fair costs (i.e., purchasing of food; drawings, raffles, or door prizes for attendees which exceed the \$15 nominal value

requirement) as long as the recognition of the donation is to a number of entities (not just one particular MA organization); and

- Market multiple lines of business in Medicare Advantage.

Medicare Advantage Organizations may not do the following:

- Give sales presentations;
- Collect enrollment applications. (Although application forms may be distributed, they may not be collected during Health Fairs);
- Collect names/addresses of potential enrollees. However, as noted above, they may distribute application forms and reply cards;
- Compare their benefits against other health plans. However, they may use comparative information which has been created by CMS (such as information from CMS' Web site) or information/materials which have been approved by CMS (i.e. the standardized Summary of Benefits);
- Third party created materials may not be used, unless they have been approved by CMS in advance; and
- Give individual gifts with a retail value of more than \$15.00.

50.2 - Specific Guidance About Provider Promotional Activities

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

Some Medicare health plans use their providers to help them market their Medicare product. As used in this chapter, the term “provider” means all Medicare health plan-contracting health care delivery network members; e.g., physicians, hospitals, etc. The purpose of this section is to specify what marketing practices in this area meet both CMS requirements and the needs of the Medicare health plans with respect to entities considered providers by Medicare health plans.

In general, providers should only market in their capacity as a member of the plan's network and only in coordination with the Medicare health plan (for example, providers/provider groups could co-sponsor an open house or a health fair with a Medicare health plan, or could cooperatively advertise on TV).

Marketing by a plan provider shall be deemed to be marketing by the Medicare health plan. Therefore, Medicare health plans should stipulate in their contracts with providers that any coordinated marketing to be carried out by the provider must be done in accordance with all applicable CMS marketing guidelines. All marketing materials describing the Medicare health plan in any way must have the Medicare health plan's

name or logo as well as the provider's/provider group's name or logo and adhere to the guidelines in this chapter. Refer to [§60.4.1](#) for information about approval of provider marketing materials (benefit-providing third party marketing materials).

The CMS is concerned with provider marketing for the following reasons:

- Providers are usually not fully aware of all Medicare health plan benefits and costs; and
- A provider may confuse the beneficiary if the provider is perceived as acting as an agent of the Medicare health plan vs. acting as the beneficiary's provider.

Providers may face conflicting incentives when acting as a Medicare health plan representative since they know their patients' health status. Desires to either reduce out-of-pocket costs for their sickest patients, or to financially gain by enrolling their healthy patients may result in recommendations that do not address all of the concerns or needs of a potential Medicare health plan enrollee.

There are some permissible delegated provider marketing activities, however. Listed below are some requirements for these, and the reasons they are permitted:

1. **Health Fairs** - At health fairs, provider groups and individual providers can give out Medicare health plan brochures including enrollment applications. Because they may not be fully aware of all benefits and costs of the various Medicare health plans, providers or their representatives cannot compare benefits among Medicare health plans in this setting. In addition, applications may not be taken at health fairs. (See the discussion of health fairs and health promotion events in [§50.1.3](#) above.)
2. **Provider Office Activities and Materials** - In their own offices, physicians and other health care providers can give out Medicare health plan brochures, and posters announcing plan/organization affiliation. However, they cannot give out or accept applications. Providers cannot offer inducements to persuade beneficiaries to join Medicare health plans or to steer beneficiaries to a specific Medicare health plan.

While providers are prohibited from giving and accepting applications in the health care setting, the Medicare health plans and provider representatives may conduct sales presentations and give and accept applications in health care settings as long as the activity takes place in the common areas of the setting, and as long as patients are not misled or pressured into participating in such activities. Common areas, where marketing activities are allowed, would be areas such as hospital cafeterias, community or recreational rooms, and conference rooms.

Regulations prohibit sales presentations and the acceptance of applications in areas where patients primarily intend to receive health care services. These

restricted areas would include, but not be limited to, waiting rooms, exam rooms, nursing resident rooms, and hospital (patient) rooms.

In addition, providers cannot offer anything of value to induce Medicare health plan enrollees to select them as their provider. When patients seek information or advice from their own physician regarding their Medicare options, physicians may engage in this discussion. Because physicians are usually not fully aware of all Medicare health plan or Original Medicare benefits and costs, they are advised to additionally refer their patient to other sources of information, such as 1-800-MEDICARE, the State Health Insurance Assistance Program, and/or specific health plan/MA organization marketing representatives. Additional information can also be found on CMS' Web site, <http://www.medicare.gov/>. Physicians are permitted to printout and share information with patients from CMS' Web site.

3. **Providers/Provider Group Affiliation Information-** Providers/provider groups can announce a new affiliation with a Medicare health plan to their patients. An announcement to patients of a new affiliation which names only one Medicare health plan may occur only once. Additional contacts from providers to their patients regarding affiliation must include all the Medicare health plans with which the provider contracts. This includes, for example, annual affiliation announcements, announcements that certain affiliations have terminated, and the display of Medicare health plan brochures/posters. If these communications describe Medicare health plans in any way (as opposed to just listing them), they must be prior approved by CMS (see below).
4. **Providers/Provider Group Comparative/Descriptive Information -** Providers/provider groups may provide printed information to their patients comparing the benefits of different Medicare health plans with which they contract. Such materials must have the concurrence of all Medicare health plans involved and must be prior approved by CMS. The Medicare health plans may want to determine a lead Medicare health plan to coordinate submission of these materials. CMS continues to hold the Medicare health plans responsible for any comparative/descriptive material developed and distributed on their behalf by their contracting medical groups and other health care providers. The providers/provider groups may not health screen when sending out such information to their patients. The reason for this is that any material sent to beneficiaries that talks about Medicare health plans is marketing and health screening is a prohibited marketing activity.
5. **Providers/Provider Group Web Sites -** Providers/provider groups may provide links to Medicare health plan enrollment applications and/or provide downloadable enrollment applications as long as the site provides the links/downloadable formats to enrollment applications for all Medicare health plans with which the provider/provider group participates.

The “**Medicare and You**” Handbook or “**Medicare Compare Information**” (from CMS’ Web site, www.medicare.gov), may be distributed by providers/provider groups without additional approvals. There may be other documents that provide comparative/descriptive material about health plans, are of a broad nature, and are written by CMS or have been prior approved by CMS. These materials may be distributed by Medicare health plans and providers without further CMS approval. Please advise your Medicare health plan providers and provider groups of the provisions of these rules.

50.3 - Specific Guidance About the Use of Independent Insurance Agents

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

The CMS recognizes that independent insurance agents can provide a necessary service to Medicare beneficiaries and potential enrollees. They can also be a valuable resource in helping to reach low-income and rural populations, persons with disabilities, and other special populations. Therefore, CMS urges Medicare health plans to consider requiring specific cost/MA training for their contracted agents. This will ensure that appropriate information is being delivered to Medicare beneficiaries and potential enrollees.

Please note that CMS is aware that sales by independent insurance agents are typically tied to compensation, and that agents are often given incentives to steer enrollees towards the carrier offering the most compensation. Further, independent insurance agents may be in a unique position to “cherry pick,” given their often longstanding relationships with clients.

Marketing by an independent insurance agent shall be deemed to be marketing by the Medicare health plan. Therefore, Medicare health plans should stipulate in their contracts with independent insurance agents that any coordinated marketing to be carried out by the agent must be done in accordance with all applicable CMS marketing guidelines. Refer to §60.3.1 for information about approval of marketing materials prepared by independent insurance agents (non-benefit-providing third party marketing materials).

50.3.1 – Guidance on the State licensure of MA marketing representatives

MA organizations must employ only marketing representatives meeting State certification/licensure requirements.

50.4 - Answers to Frequently Asked Questions About Promotional Activities

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

1. **Q** - We purchased books on health maintenance that we plan to give away to anyone attending one of our marketing presentations, regardless of whether or not they enroll in our Medicare health plan. Because we purchased a large number of

these books, we were able to buy them at a cost of \$14.99 per book. However, on the inside jacket, the retail price is shown as \$19.99. May we give these books away at our marketing presentation?

A - No. The retail purchase price of the book is \$19.99, which exceeds CMS' definition of nominal value.

2. **Q -** We are participating in a health fair during which we will have marketing staff present. During the fair, we will offer a number of free health screening tests to people who attend. The value of these tests, if purchased, would be considerably more than \$15. Is this permissible?

A - No. You may not offer these tests for free because their value exceeds CMS' definition of **nominal** value.

3. **Q -** At our Medicare health plan, we offer gifts of nominal value to people who call for more information. We then offer additional gifts if they come to marketing events. Each of the gifts meets CMS' definition of nominal value, but taken together, the gifts are more than nominal value. Is this permissible?

A - Yes.

4. **Q -** Listed below are some possible promotional items to encourage people to attend marketing presentations. Are these types of promotions permissible?

- Meals
- Day trips
- Magazine subscriptions
- Event tickets
- Coupon book (total value of discounts is less than \$15)

A - Yes. All these promotional items are permissible as long as they are offered to everyone who attends the event regardless of whether or not they enroll and as long as the gifts are \$15 or less. Cash gifts are prohibited including charitable contributions made on behalf of people attending a marketing presentation, and including gift certificates that can be readily converted to cash, regardless of dollar amount.

5. **Q -** Can a Medicare health plan advertise eligibility for a raffle or door prize of more than nominal value for those who attend a marketing presentation if the total value of the item is less than \$15 per person attending?

A - No. You cannot have a door prize of more than nominal value. Such gifts or prizes are prohibited by CMS. However, the raffle or door prize can exceed the \$15 limit if the organization is jointly sponsoring the prize with other Medicare health plans at a health fair. See §50.1 for a discussion of rules pertaining to health fairs.

6. **Q** - What about post-enrollment promotional activities? Are there any rules prohibiting such items or activities as coupon books, discounts, event tickets, day trips, or free meals to retain enrollees?

A - Currently, the Medicare Managed Care Manual states that Medicare health plans may not offer post-enrollment promotional items that in any way compensate beneficiaries for lower utilization of services. Any promotional activities or items offered by Medicare health plans, including those that will be used to encourage retention of members, must be of nominal value, must be offered to all eligible members without discrimination, and must not be in the form of cash or other monetary rebates. The same rules that apply to pre-enrollment promotional activities apply to post-enrollment promotional activities.

7. **Q** - Can Medicare health plans provide incentives to current members to receive preventive care and comply with disease management protocols?

A - Yes, as long as the incentives are:

- Offered to current members only;
- Not used in advertising, marketing, or promotion of the Medicare health plan;
- Provided to promote the delivery of preventive care; and
- Are not cash or monetary rebates.

NOTE: If these products are in the CMS approved contracted MA organization benefit package (BIDS and PBP) under “Preventive Services,” the provision of such incentives are within the purview of the medical management philosophy of the MA organization and do not require additional review by CMS for marketing accuracy/compliance. The nominal value rule **does not** apply.

8. **Q** - Can a Medicare health plan offer reductions in premiums or enhanced benefits based on the length of a Medicare beneficiary’s membership in the Medicare health plan?

A - No. Longevity of enrollment is not a basis for reductions in premium or enhanced benefits. ¹⁸

9. **Q** - Can a Medicare health plan provide discounts to beneficiaries who prepay premiums for periods in excess of 1 month?

A - No. Medicare health plans cannot provide any discounts to Medicare beneficiaries for prepayment of premiums in excess of 1 month.

10. **Q** - Can a Medicare health plan take people to a casino or sponsor a bingo night at which the member's earnings may exceed the \$15 nominal value fee?

A - No. The total value of the winnings may not exceed \$15 and the winnings **cannot be in cash or an item that may be readily converted to cash.**

11. **Q** - Can Medicare health plans send a \$1 lottery ticket as a gift to prospective members who request more information?

A - Offering a \$1 lottery ticket to prospective members violates the "no cash or equivalent" rule discussed above, whether or not the person actually wins since, generally, the "unscratched" ticket has a cash value of \$1.

12. **Q** - Can Medicare health plans pay beneficiaries that sign up to be "ambassadors" a flat fee for transportation?

A - The Medicare health plan may reimburse the beneficiary for any actual, reasonable transportation costs but must not pay the beneficiary a flat fee for transportation. If the Medicare health plan employs a beneficiary to be an "ambassador" and travel reimbursement is part of the employment compensation, then CMS has no oversight over this issue.

13. **Q** - Can Medicare health plans that own nursing homes conduct health fairs and distribute enrollment forms to nursing home residents?

A - Yes, organizations that own nursing homes may conduct health fairs and distribute enrollment forms if the sales presentations are confined to a common area (i.e., community or recreational rooms) or if a member volunteered for an individual presentation. Promotional activities and sales presentations cannot be made in individual resident rooms without a prior appointment for a "home" visit. Such activities would be considered door-to-door solicitation and are prohibited. The organization is required to meet all health fair/sales presentation and enrollment requirements as currently outlined in this chapter and regulations.

14. **Q** - Can physician groups that contract with Medicare health plans hire marketing firms to cold call from non- Medicare health plan member listings?

A - Yes, as long as the marketing guidelines for provider marketing are followed.

15. **Q** – Can Medicare health plans obtain leads from providers?

A – Yes, a provider may provide lists of their patients to Medicare health plans for marketing purposes. However, the CMS prefers that these lists be complete patient lists (for example, not just lists of patients over 65) in order to prevent health care screening. The list may contain contact information (name, address, phone number) but must not contain health/health status information. The provider is responsible for ensuring that it does not violate any HIPAA rules prior to providing such lists to the organization.

60 - Other Marketing Activities

(Rev. 42, 01-09-04)

This section outlines requirements for a variety of marketing activities. In particular, this section is divided into four sub-sections:

60.1 – Specific Guidance on Marketing Activity for MA Special Needs Plan (SNP)

60.2--Provides requirements for value-added items and services;

60.3 – Provides requirements for marketing multiple lines of business;

60.4 – Provides requirements for review of third party marketing materials, and

60.5 – Provides requirements for marketing to non-English speaking populations.

60.1. Specific Guidance on Marketing Activity for MA Special Needs Plan (SNP)

The MMA (Medicare Modernization Act of 2003) allows MA organization to offer plans that serve special needs individuals. The legislation designates two specific segments of the Medicare population as special needs individuals. These are institutionalized individuals and those entitled to Medical Assistance under a State Plan under Title XIX. Additionally, MMA allows the Secretary to designate other chronically ill or disabled beneficiaries as “special needs beneficiaries” to allow plans to enroll additional high-risk groups who would benefit from a specialized MA plan.

Important note: All MA SNPs must follow the marketing guidelines in Chapter 3 in terms of the Marketing review process.

If SNP use contracted providers to identify eligible individuals, this then falls into “Provider marketing”. SNPs are required to follow the specific guidance covered under provider marketing in Section 50.2 of this manual.

A. Dual Eligible SNP

- *Dual eligible SNP may work with their respective states to identify an acceptable method of targeting dual eligible beneficiaries. In the event, as with any MA organizations, the SNP must market to all eligible individuals.*
- *A Medicare Advantage Organization with multiple plans must ensure that the active dual eligible members in non-SNPs are not steered into joining the SNP.*
- *While SNP are permitted to market to all eligible individuals, it is prohibited from engaging in any activities that could mislead or confuse Medicare beneficiary is prohibited.*
- *The marketing materials for the dual eligible SNP must be targeted only to the specific dual eligible individuals and all materials must clearly identify the eligibility requirements for that plan.*
- *While CMS provides a model Evidence of Coverage (EOC) for HMOs, PPOs and Medicare cost plans, SNP can develop a comprehensive EOC based on their uniqueness to include Medicaid benefits. If SNP choose to develop a comprehensive EOC, coordination must take place with the State Medicaid Agency for review of Medicaid benefits. Additionally, anytime SNP marketing materials mention Medicaid or how its benefits interface with the State Medicaid program. We encourage SNP to coordinate their activities with the State. The Regional Office is only responsible for review of marketing materials that specify Medicare benefits and information on Medicare program.*

B. Institutional SNP

By definition, institutional SNP will enroll a limited group of beneficiaries and may also have limited enrollment options (e.g., the plan may have only one contracted long term care facility in a county with a few open beds.) Given these conditions, CMS may not require such a SNP to broadly market its plan. However, the overall Medicare population, as well as beneficiaries who meet the SNP eligibility requirements, must have reasonable access to information describing all MA plans including institutional SNP that are available throughout its service area. Importantly, information on these plans must be made available on CMS web site so that interested beneficiaries (or their families) can identify institutional SNPs that are available in the service area.

60.2 - Specific Guidance About Value-Added Items and Services

(Rev. 9, 04-01-02)

Value-Added Items and Services (VAIS) are items and services offered to MA plan enrollees, by an MA organization that *does not meet the definition* of “benefits” under the M+ C program and may not be funded by Medicare program dollars. Nonetheless, VAIS may be of value to some beneficiaries, and we do not wish to deprive Medicare enrollees of access to items and services commonly available to commercial enrollees. Examples of VAIS may include, but are not limited to discounts in restaurants, stores, entertainment, and travel or discounts on health club memberships and on insurance policy premiums. The CMS permits VAIS to be offered to MA enrollees under the rules outlined below.

The VAIS are partly defined by what they are not - they are not benefits under the MA program. The MA regulations at 42 CFR 422.2 define benefits using a three-prong test:

1. Health care items or services that are intended to maintain or improve the health status of enrollees;
2. The MA organization must incur a cost or liability related to the item or service and not just an administrative cost; and
3. The item or service is submitted and approved through the BID (BIDS) process.

All three parts of the definition must be met for an item or service to be considered a benefit under MA. If an item or service fails to meet one or more of these parts, it is not a benefit. However, it may be offered to MA enrollees as a VAIS, subject to the restrictions that follow.

The following examples demonstrate the application of the three-prong test:

Example 1:

An MA organization arranges for its enrollees a discount on all daily supplements purchased from a health food chain. The health food chain does not charge the MA organization for this discount, and requires the MA organization to develop a verification system so the health food chain can identify the organization’s enrollees. The MA organization incurs an administrative cost to develop the verification system, but does not incur a cost of providing or furnishing the daily supplement. Therefore, the discount on daily supplements would be considered a VAIS. The BIDS submitted by the MA organization may not reflect (as a Medicare enrollee benefit cost) the administrative cost.

Example 2:

An MA organization arranges for its enrollees a 10 percent discount on eyeglasses purchased from a group of eye doctors. The physician group charges the MA organization for the group's cost to administer the program, and requires the MA organization to develop a verification system to identify the organization's enrollees. The MA organization incurs two costs:

1. The MA organization pays the physician group's administrative cost of administering the program; and
2. The MA organization incurs the administrative cost for developing and providing the verification system.

Both of these costs are administrative in nature, and the MA organization does not incur a cost of providing or furnishing the eyeglasses. Therefore, the discount on eyeglasses is considered a VAIS. The BIDS submitted by the MA organization should not reflect (as a Medicare enrollee benefit cost) either of the two administrative costs.

Example 2a:

Given the same circumstances outlined in Example 2 above, except, the amount paid to the physician group by the MA organization includes an amount for the cost of the eyeglasses. In this case, the MA organization does incur a cost of providing or furnishing the eyeglasses. Therefore, the 10 percent discount on eyeglasses is not considered a VAIS. The BIDS submitted by the MA organization should reflect the administrative costs it incurs and the amount paid to the physician group. The marketing materials should describe the eyeglass benefit with a 90 percent coinsurance. As with all benefits offered as part of an MA plan, the Medicare enrollee must be afforded appeal rights for this benefit.

60.2.1 - Restrictions on Value-Added Items and Services

(Rev. 15, 09-27-02)

The MA organizations may make VAIS available to Medicare enrollees in accordance with the following guidelines:

1. VAIS must be offered uniformly to all MA plan enrollees and potential enrollees.
2. MA organizations may not describe VAIS as benefits. In accordance with 42 CFR 422.80(e) (iv), which states that MA organizations may not engage in activities that could mislead or confuse Medicare beneficiaries, the MA organization may not claim or imply that the VAIS are recommended by or endorsed by CMS or Medicare.

3. The MA organization must maintain confidentiality of enrollee records in accordance with 42 CFR 422.118 and other applicable statutes and regulations. The use or distribution of information about enrollees for non-plan purposes is prohibited. The MA organization is thus prohibited from selling names, addresses, or information about the individual enrollees for commercial purposes. If the MA organization uses a third party to administer VAIS, the MA organization is ultimately responsible for adhering to and complying with confidentiality requirements.

60.2.2 - Relationship of Value-Added Items and Services (VAIS) to Benefits and Other Operational Considerations

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

Medicare health plans can market, either through oral presentations or written materials, Value-Added Items and Services (VAIS). Organizations can also mention VAIS in their newsletters. With one exception, VAIS may not appear in the PBP, the Standardized SB, the ANOC or the EOC. The exception is with the discount prescription drug program, which can be mentioned in the EOC, the ANOC and section 3 of the SB, as long as they include the required disclaimers. If the program is mentioned, the marketing material must clearly state (in the location that the program is described) that the discount prescription drug program will be available for the entire contract year.

Any description of VAIS must be preceded by the following prominently displayed language:

The products and services described below are neither offered nor guaranteed under our contract with the Medicare program. In addition, they are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the [Name of plan] grievance process.

Organizations may include VAIS along with their ANOC, SB, and/or EOC in one bound brochure as long as the value-added services are clearly distinct from the ANOC, SB, or EOC (such as on a different color piece of paper), and the information on value-added services includes all the disclaimers required in this chapter.

Because VAIS does not meet the definition of a benefit under the MA program, neither “benefit” nor associated administrative costs may appear in the BIDS. Furthermore, because they are not contained within the contracted health benefits package, these services are not subject to the Medicare appeals process. VAIS may not be described in Medicare Compare or the “Medicare and You” handbook.

The CMS will not require prior approval of materials describing VAIS, since VAIS are not benefits as described within CMS regulations and therefore are not technically within CMS purview. The CMS will review these materials on monitoring visits to ensure

compliance with these requirements. The CMS may initiate a monitoring visit if it becomes aware that materials have been distributed describing VAIS without the appropriate disclaimers or in violation of the requirements stated herein. CMS will also investigate complaints by beneficiaries regarding VAIS, just as it would other possible violations of CMS requirements.

60.2.3 - Value Added Items and Services Provided to Employer Groups

(Rev. 9, 04-01-02)

Value-added items and services may be offered to employer groups. Value-added items and services are offered outside the core benefit package, thus they are outside of CMS' purview.

60.2.4 - Application to §1876 of the Social Security Act (the Act) Cost Plans

(Rev. 9, 04-01-02)

Value-added items and services may be offered by §1876 cost plans. However, VAIS are non-covered services for which §1876 cost plans are not reimbursed

60.3 - Marketing of Multiple Lines of Business

(Rev. 42, 01-09-04)

MA organizations may market multiple lines of business in accordance with the following.

Direct mail: Direct mail health plan/MA organization marketing materials sent to current members describing other lines of business should contain instructions describing how individuals may opt out of receiving such communications. Health plan/MA organizations need not describe this opt-out provision in every piece included in the direct mailing, but they must include it on at least one piece in each direct mailing they conduct. Health plan/MA organizations should make reasonable efforts to ensure that all individuals (including non-members) who ask to opt out of receiving future marketing communications, are not sent such communications.

NOTE: These instructions regarding “opting out” of receipt of direct mail apply only to information that does not require prior authorization, as discussed in §60.2.1.

With one exception (mentioned below), health plans/MA organizations may advertise multiple lines of business in direct mail marketing materials within the same document as the one that is advertising the plan product, as long as the non-plan lines of business are clearly and understandably distinct from the plan product. For example, the document

might highlight the name of the plan product in bold and underlined font and then include a paragraph to describe the product in “regular” font, then it would go on to highlight the name of a Medigap product in bold and underlined font followed by a paragraph describing the Medigap product in “regular” font. Please keep in mind that the direct mail materials advertising multiple lines of business still should allow the beneficiary the choice of opting out of receiving future notices about non-MA products. Also, if a health plan/MA organization advertises non-plan products with a plan product, it must pro-rate any costs so that costs of marketing non-plan products are not included as “plan-related” costs on BID (BIDS) proposal submissions.

Organizations that offer more than one type of Medicare Advantage products (HMOs, PPOs) may market all of the products as a “family of products.” In this case, the marketing materials must clearly distinguish between the type of product, eligibility requirements, how to obtain services (lock-in, preferred vs. non-preferred benefits), and any out-of-pocket maximums, and specify the benefits to which they apply. Furthermore, multiple product advertising may only be conducted in areas where those products share service areas. We recognize that service areas may not perfectly align. When this occurs, the MA organization should make a reasonable effort to market the “family of products” only in counties that all products share.

Direct Mail Exception

While health plans/MA organizations may mention non-plan lines of business at the time they send a plan nonrenewal notice, they may only do so using separate enclosures in the same envelope. Health plans/MA organizations must not include mention of the non-plan lines of business within the actual nonrenewal notice. The purpose of this exception is to ensure that the nonrenewal notice gives beneficiaries focused information only about the plan nonrenewal.

Health plans/MA organizations must not include enrollment applications for non-plan lines of business in any package marketing its MA products, as beneficiaries might mistakenly enroll in the other option thinking they are enrolling in a health plan/MA organization. Also, if information regarding cost/MA products and non-plan lines of business are included in the same package, postage costs must be prorated so that costs of marketing non-plan products are not included as “plan-related” costs on BIDS proposal submissions.

Television: Health plans/MA organizations may market other lines of business concurrently with plan products on television advertisements, as long as those products are separate and distinct from the plan product.

Internet: Health plan/MA organizations may market other lines of business concurrently with plan products on the Internet, though to avoid beneficiary confusion, the health plan/MA organization must continue to maintain a separate and distinct section of their Web site for plan information only.

The CMS will review the MA organization's Web pages to ensure that MA organizations are maintaining the separation between MA plan information and information on other lines of business.

60.3.1 - HIPAA and the Marketing of Multiple Lines of Business

(Rev. 20, 04-04-03)

In general, a health plan/MA organization does not need to obtain authorization from beneficiaries to market its own health-related, value-added products. This includes other lines of business offered by the same covered entity and its subcontractors (business associates) doing business on behalf of the covered entity. However, a health plan/MA organization must obtain authorization from beneficiaries under certain circumstances. For example, authorization is needed if the product is a pass-through discount, a product offered by an entity other than the covered entity or outside of a business associate contract, an accident only policy, a life insurance policy, or is not in the plan of benefits because it is not a health related item or service. For additional information regarding HIPAA, go to <http://www.hhs.gov/ocr/hipaa/>.

60.4 - Third Party Marketing Materials

(Rev. 20, 04-04-03)

From time to time, a third party may prepare marketing materials for a health plan's/MA organization's membership and/or supply those materials to the membership. These materials are known as "third party marketing materials," and can be prepared both by benefit/service providing and non-benefit/service providing third parties. Marketing review of these materials is dependent upon the type of third party, as outlined in the remainder of this section.

60.4.1 - Benefit Providing Third Party Marketing Materials

(Rev. 20, 04-04-03)

A benefit/service-providing third party is an entity that either administers or covers the health care benefits of the health plan's/MA organization's Medicare membership or provides health care services to the health plan's/MA organization's Medicare membership. Some examples of benefit/service-providing third party entities would be employer groups, drug companies, or nursing homes, etc.

Other than MA employer group marketing materials, CMS reviews all marketing materials prepared by benefit/service-providing third party entities if they will be used by the health plan/MA organization for its membership (as stated in §20.2, MA organizations are waived from having marketing materials reviewed for employer group members). Marketing materials must be submitted to CMS via the health plan using the

materials, and may not be submitted directly by the third party to CMS. The benefit/service-providing third party should submit the material via the health plan/MA organization with the largest membership.

In the event a benefit/service providing third party works with multiple health plans to provide the **same** marketing material to each organization's membership, the material need only be approved by CMS once, as long as that material is not for use by health plans/MA organizations with dual eligible members (since dual eligible marketing materials may need to vary by state). Once CMS has approved the material, it is considered approved for all other health plans/MA organizations with which the third party works. The third party or the health plan/MA organization may change the product name, telephone numbers, addresses, and/or tracking codes on the material and a new approval will not be necessary.

Please note that as part of its business relationship with other health plans/MA organizations the third party must inform the other health plan/MA organization that it would like to use the CMS-approved material for its membership. Also, the health plan/MA organization and the third party should work together to determine whether the material will be used for the health plan's membership or whether new materials need to be developed.

If a health plan/MA organization intends to have the third party provide the pre-approved material to its membership, it must send an "FYI" copy of that material to the Regional Office (RO) for the RO files.

The CMS does not review marketing materials originated by non-benefit providing third party entities. For the purpose of marketing review, non-benefit providing third party entities are defined as any organizations or individuals that supply information to an MA organization's membership which is paid for by the MA organization or by themselves. An example of a non-benefit providing third party would be a managed care research firm that provides managed care data relating to managed care organizations.

If a non-benefit providing third party wishes to market to MA membership, they must submit their materials to the MA organization, who in turn, can distribute the materials to their membership. It is the responsibility of the MA organization to ensure that all non-benefit providing third party marketing materials contain the disclaimer, "Medicare has neither reviewed, nor endorses this information." This disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size and style as the commercial message.

60.4.2 - Non-Benefit/Service Providing Third Party Marketing Materials

(Rev. 20, 04-04-03)

A non-benefit/service providing third party is an entity that neither administers the health care benefit nor provides health care services to the health plan's/MA organization's Medicare membership. For the purpose of marketing review, non-benefit/service providing third party entities are organizations or individuals that supply information to a health plan's/MA organization's membership which is paid for by the health plan/MA organization or by themselves. An example of a non-benefit/service providing third party could be a research firm that provides comparative data relating to managed care organizations.

The CMS does not review marketing materials originated by non-benefit providing third party entities.

If a non-benefit/service providing third party wishes to market to health plan/MA organization, membership, they must submit their materials to the health plan/MA organization, which in turn, can distribute the materials to their membership. It is the responsibility of the health plan/MA organization to ensure that these marketing materials contain the disclaimer, "Medicare has neither reviewed, nor endorses this information." This disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size and style as the commercial message.

60.5 - Marketing Material Requirements for Non-English Speaking Populations (QISMC Standard 2.3.3.2)

(Rev. 11, 08-15-02)

Health plans/MA organizations should make marketing materials available in any language that is the primary language of more than 10 percent of the geographic area. In addition, basic enrollee information should be made available to the visually impaired.

60.5.1 - Review of Marketing Materials in Non-English Language or Braille

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

In general, for marketing with materials that contain non-English or Braille information (in whole or in part), the health plan must submit the non-English or Braille version of the marketing piece, an English translation of the piece, and a letter of attestation. However, in an effort to reduce the burden on the organization and CMS, the organization may choose to submit an English version for approval first, and then submit the non-English or Braille version along with the letter of attestation. This way, any

changes or revisions that are made to the English version will be accurately reflected in non-English materials.

The letter of attestation must be signed and certified by an authorized official employed by the organization, and must attest that the translation conveys the same information and level of detail as the corresponding English version. (See §60.5.2 for a model attestation letter.)

All organizations will be subject to verification monitoring review and associated penalties for violation of CMS policy. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing review of non-English materials on an “as needed” basis. If materials are found to be inaccurate or do not convey the same information as the English version, organizations may not continue to distribute materials until revised materials have been approved. If multi-region organizations have submitted materials in English to their lead RO and the materials have been approved, the same materials in other languages or Braille may be used in other regions.

The following applies to organizations on File and Use:

- When an organization is on File and Use, it is on File and Use for both English and non-English materials. Therefore, continual violations in non-English materials could be grounds for placing an organization on probation.
- When an organization is on File and Use probation, the probation is for both English and non-English materials. If File and Use status is revoked, it is revoked for both English and non-English materials.
- If an organization is on File and Use, it must submit English and non-English versions of materials 5 calendar days prior to their use.

60.5.2 - Model Attestation

(Rev. 60, Issued 08-20-04, Effective: August 08, 2004/Implementation: N/A)

**ATTESTATION OF TRANSLATED NON-ENGLISH MATERIALS
FOR MEDICARE HEALTH PLANS**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (insert organization name), hereafter referred to as the Medicare Health Plan, governing the operations of the following health plan: (insert plan and H number), the Medicare health plan hereby attests that the non-English version(s) submitted in the attached, convey the same information and level of detail as the corresponding English version.

The Medicare health plan acknowledges that the information concerning the translation(s) described below is for the use of and correspondence to the beneficiary and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The Medicare health plan is submitting to CMS the attestation with the following materials: (INSERT MATERIAL IDENTIFICATION NUMBERS).

Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in these documents are accurate, complete, and truthful.

(NAME & TITLE [CEO, CFO, or delegate])

on behalf of

(NAME OF MEDICARE^E HEALTH PLAN)

DATE

Endnotes

(Rev. 59, 08-06-04)

¹ The primary CMS/health plan contractual frame of reference in Chapter 3 is of a Medicare Advantage organization offering a coordinated care plan. Where applicable, alternative language is provided for cost plans as well as scenarios involving the point-of-service (POS) and Visitor Program features which may be applicable for MA and/or cost plans.

² The guidelines throughout this document apply to Medicare Advantage Organizations (MA organizations) as well as Section 1876 of the Act cost contractors, unless stated otherwise. Therefore, for ease of review and reference, the term “Medicare health plan” is used throughout the document to include requirements specific to both Medicare Advantage Organizations and §1876 cost contractors.

³ This endnote has been deleted.

⁴ This endnote has been deleted.

⁵ This endnote has been deleted.

⁶ CMS has the discretion to disapprove language based on site visit reviews identifying substantial deficiencies in Medicare health plan operations.

⁷ A member of the Medicare health plan may use a superlative in relating their personal experience with the Medicare health plan so long as the testimonial is preceded with the phrase “in my opinion” (e.g., “I have been with the organization for 10 years and in my opinion they have given me the best care possible.”) If the member does not preface the superlative statement with the “in my opinion” phrase, the member must substantiate the statement with an acceptable qualifying information source.

⁸ Note 8 has been deleted.

⁹ In accordance with Chapter 3, this information should be provided in at least 12-point font size.

¹⁰ The MA organizations may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in provider’s addresses and phone numbers. However, in accordance with 42 CFR 422.111(c), MA organizations must make a good faith effort to disclose any changes to the provider information upon request and, under 422.111(e), must make a good faith effort to provide written notice at least 30 calendar days before the termination effective date. MA organizations should consult the MA regulations for further information.

¹¹ In accordance with Chapter 3, the applicable TDD/TTY number must also be provided, including the hours of operation.

¹² The CMS' monthly capitation rate to an MA organization for a plan member is higher for an enrollee who is a Medicaid recipient because, statistically, the Organization incurs higher medical costs due to higher utilization than that of a non-Medicaid recipient. However, because CMS created the QI-1 category of Medicaid recipients after it established the standard monthly payment upon which it bases all capitation payments, CMS policy is to not pay the Medicaid adjustment factor for this group.

¹³ Since Medicare health plans are primarily responsible for conducting outreach, Chapter 3 has been written targeting that audience. However, if the Medicare health plan contracts with another entity for any part of this outreach, the contracting entity must abide by Chapter 3 as well.

¹⁴ The CMS considers the following to be examples of substantive changes to an outreach program that would make the proposal and/or attached member materials an "initial" proposal: changes to the steps involved in the outreach process, changes to the language in the outreach letters, revisions to the telephone scripts, changes to the network of subcontractors participating in the outreach efforts, etc. CMS considers the following to be examples of changes allowable without designating the proposal as "initial": contact telephone numbers, letterhead, mailing dates and targeted member numbers, updates to income and resource criteria and benefit levels as updated by the State.

¹⁵ Outreach proposals should go to CMS , Division of Medicare Health Plans, 75 Hawthorne Street 4th Floor, , San Francisco, CA 94105-3918, Attn: Eileen Turner, Manager, Dual Eligible Proposal; fax:415-744-3761.

¹⁶ Section 1851(e)(3) of the Act and 42 CFR 422.10(b).

¹⁷ An application form may be either:

1. A specifically designed enrollment application form which is attached to Medicare health plan marketing materials; or
2. A standard Medicare health plan enrollment application form with instructions that the form must be mailed back to the Medicare health plan .

The key feature of the application form is that it must be completed by the beneficiary in the absence of Medicare health plan marketing influences and returned to the Medicare health plan by mail. (Self-addressed, postage paid, return envelopes may be provided by the Medicare health plan).

¹⁸ This "no" statement also applies to "zero" premium plans that might want to award a nominal value gift as a reward for longevity of enrollment.